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DEMOGRAPHIC CHARACTERISTICS AMONG PATIENTS WITH ANTI-TUBERCULOSIS DRUG INDUCED PERIPHERAL NEUROPATHY

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ABSTRACT

Background: In India, Tuberculosis has been mentioned in the Vedas and the old Ayurvedic scriptures. Historically speaking, fight against Tuberculosis in India can be broadly classified into three periods: early period, before the discoveries of x-ray and chemotherapy; post-independence period, during which nationwide Tuberculosis control programs were initiated and implemented; and the current period, during which the ongoing WHO-assisted Tuberculosis control program is in place. Tuberculosis incidence is seasonal, with peaks occurring every spring and summer. The reasons for this are unclear, but may be related to vitamin D deficiency during the winter. There are also studies linking tuberculosis to different weather conditions like low temperature, low humidity and low rainfall. It has been suggested that tuberculosis incidence rates may be connected to climate change. Those at high risk thus include: people who inject illicit drugs, inhabitants and employees of locales where vulnerable people gather (e.g., prisons and homeless shelters), medically underprivileged and resource-poor communities, high-risk ethnic minorities, children in close contact with high-risk category patients, and health-care providers serving these patients. Factors contributing to this include higher prevalence of predisposing health conditions and behaviours, and overcrowding and poverty. In some Canadian aboriginal groups, genetic susceptibility may play a role. Methods: Quasi-experimental design (one group pre-test post-test design) was recruited by non-probability purposive sampling technique used for the present study. Necessary administrative permission was obtained from the concerned authority. The Structured interview schedule was used to elicit the baseline data. Result: The study revealed that among 180 Tuberculosis patients, age, gender, marital status, family type, occupation and history of hospitalization was not significantly associated, where as education found statistically significant at 0.05 levels. It is observed that the majority of the respondents 46.7% were in the age group of 35-44 years, whereas 38.3% of the respondents in the age group of 45-54years. In relation to age, 52.2% of the respondents were male and 47.8% were females. It is observed that 100% of respondents were from joint families, it is noticed that majority 96.7% of the respondent had schooling, 3.3% had above schooling, It is noticed that majority 76.7% of the respondents were farmer, 20.5% were labor/daily wage, 2.8% had business. It is noticed that majority 28.3% of the

respondents had history of hospitalization and 71.7% had no history of hospitalization. Conclusion:-The study concluded that the foot reflexology of anti-tuberculosis drug-induced peripheral neuropathy among Tuberculosis patients from selected community area, Ramanagara Taluk & District, Karnataka carried out the study was found to be effective in decreasing the fatigue levels among peripheral neuropathy in person with Tuberculosis patients as evidenced by the significant change between pre-test and post-test scores.

INTRODUCTION

Tuberculosis (TB) is a bacterial infection that is spread by breathing in small droplets from the coughs and sneezes of an infected person. It primarily affects the lungs, but can affect any part of the body, including the abdomen, glands, bones, and nervous system. Tuberculosis (TB) is an infection usually caused by Mycobacterium tuberculosis (MTB). Tuberculosis usually affects the lungs, but can affect other parts of the body as well. Most infections are asymptomatic and this is called latent tuberculosis. About 10% of latent infections progress to active disease, and about half of those infected die if left untreated. Typical symptoms of active tuberculosis are chronic cough with bloody mucus, fever, night sweats, and weight loss [1].

The peripheral nerves are the part of the nervous system responsible for carrying information from all parts of the body to the spinal cord and brain. Peripheral neuropathy is a condition that affects nerves and interferes with the transmission of information from different parts of the body. It affects sensory, motor and autonomic nerves and can lead to a variety of symptoms and complications. It is estimated that up to 500 million people worldwide suffer from peripheral neuropathy, a problem common in tuberculosis patients. The pathophysiology of peripheral neuropathy results from damage to the nerve body or myelin sheath, resulting in the loss of normal function and the development of disability in the affected individual. In tuberculosis, multiple factors can lead to the development of peripheral nerve injury and neuropathy [2].

Tuberculosis (TB) is one of the most ancient diseases of mankind, with molecular evidence going back to over 17,000 years. In spite of newer modalities for diagnosis and treatment of TB, unfortunately, people are still suffering, and worldwide it is among the top 10 killer infectious diseases, second only to HIV. According to World Health Organization (WHO), TB is a worldwide pandemic. It is a leading cause of death among HIV-infected people. In India, historically speaking, fight against TB can be broadly classified into three periods: early period, before the discoveries of x-ray and chemotherapy; post-independence period, during which nationwide TB control programs were initiated and were initiated and implemented; and the current period, during which the ongoing WHO-assisted TB control program is in place. Today, India's DOTS (directly observed treatment-short course) program is the fastest-expanding and the largest program in the world in terms of patients initiated on treatment; and the second largest, in terms of population coverage. Major challenges to control TB in India include poor primary health-care infrastructure in rural areas of many states; unregulated private health care leading to widespread irrational use of first-line and second-line anti-TB drugs; spreading HIV infection; lack of political will; and, above all, corrupt administration. Multidrug-resistant TB (MDR-TB) is another emerging threat to TB eradication and is a result of deficient or deteriorating TB control program. WHO with its "STOP TB" strategy has given a vision to eliminate TB as a public health problem from the face of this earth by 2050.

Tuberculosis remains a worldwide public health problem. India is the highest TB burden country with World Health Organization (WHO) statistics for 2011 giving an estimated incidence figure of 2.2 million cases of TB in India out of a global incidence of 9.6 million cases [2].

Tuberculosis is the second most important cause of adult death worldwide due to infectious disease, after HIV/AIDS. Roughly 13.2 million (new and old cases), new cases 9.2 million every year are affected globally (2018). Approximately one in every 10 of these people will develop TB disease, which typically consists of a chronic cough, severe weight loss, night sweats and progressive, irreversible lung damage. [3]

Peripheral neuropathy (PN) is a serious condition affecting the nerves that are commonly seen in patients with tuberculosis (TB).Causes of PN in patients with Tuberculosis are multiple and can include Tuberculosis itself, other co-morbid conditions, such as Human Immune-deficiency virus (HIV) disease, malnutrition, or diabetes mellitus (DM), and several anti-tuberculosis medications. The condition can manifest with a variety of symptoms, and a diagnosis can usually be made on a clinical basis. Treatment and prognosis of PN vary depending on the under lying cause, but often the condition can lead to permanent disability in individuals with Tuberculosis. For this reason, primary prevention is key as is early identification and management of symptoms. Treatment can include withdrawal of possible offending agents, vitamin supplementation, physical therapy, analgesics, and

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targeted agents, including tricyclic antidepressants, selective serotonin reuptake inhibitors, and gabapentin. Additional research is needed to better describe the morbidity and disability associated with PN in persons with Tuberculosis and to improve management strategies for persons at risk for and affected by this condition. [4]

Rates of peripheral neuropathy in the general population have been noted to be around 1.1% but as high as 6% in the elderly, although most of this data come from western countries and there is a need for more general baseline data in high-burden TB settings. Several studies have assessed the prevalence of neuropathy in persons with TB. Among persons with drug-susceptible TB (DS-TB), rates between 0 and 10% have been reported in the literature. In Swaziland, a cohort of 250 patients from one hospital with drug sensitive tuberculosis revealed a rate of 12%; however male patients had a higher rate 18% compared to females 7% ($p < 0.03$); the older the patient, the higher the rate of neuropathy (20% in those older than 45 years old compared to 9.6% in those less than 45 years old ($p = 0.01$) but no significant difference was demonstrated between those with HIV infection and those without (13% vs 11%, $p = 0.12$) probably because most of the HIV infected patients were already on ART prior to TB disease and treatment. [6]

For those with drug-resistant TB (DR-TB) much higher rates have been seen, with studies reporting rates between 13 and 17% Some of the variation in rates may be due to the different drugs used and the longer duration of treatment for DR-TB, but a recent study found that as many as 25% of patients have PN at the time they start treatment for DR-TB. [7]

Foot reflexology is a systemic practice in which a practitioner applies some pressure to any pressure points on the feet to stimulate the body and provide health benefits to different parts of the body. Foot reflexology is commonly practiced as a complementary therapy and is one of the non pharmacological therapies to alleviate our mental, emotional, and spiritual health, while improving the quality of our life. [8]

MATERIALS AND METHODS

Study Design

The research design adopted for the present study was Quanitative research approach. The research design used for the present study was one group pre-test post-test design which belongs to the quasi-experimental study.

Subjects

180 Tuberculosis patients were recruited for the present study, who met the inclusive criteria were selected through the non-probability purposive sampling technique. The study was conducted in Ramanagara Taluk & District, Karnataka, India.

Basic demographic data, Chalder fatigue scale, Michigan neuropathy scale were used as a research tool. Since it is considered to be the most appropriate instrument to elicit the response from subjects. The validity of the tool was established by experts and then proceeding with the main study. Followed by foot reflexology.

A letter requesting permission was sent to the concerned authority of the selected Community area, Ramanagara Taluk & District, Karnataka before the data collection, and permission were granted for the same. The data was collected in August 2021 at the selected Community area, Ramanagara Taluk & District. After Ethical clearance from RajaRajeswari Medical College & Hospital, IEC Committee, the data was collected from 180 Tuberculosis patients by using non-probability purposive sampling. The purpose of the tools was explained to the samples with self -introduction. After selecting the samples the study was explained & written consent was obtained from each study sample. In the initial stage the investigator has assessed the clinical variables for both the experimental & control groups followed by the Chalder fatigue scale, Michigan neuropathy scale used to assessed for peripheral neuropathy Later foot reflexology was administered for the experimental group every one-month interval the investigator was followed same procedures.

Intervention Details

The purpose of the tools was explained to the samples with self -introduction. After selecting the samples the study was explained & written consent was obtained from each study sample. In the initial stage the investigator has assessed the clinical variables for both the experimental & control groups followed by the Chalder fatigue scale, Michigan neuropathy scale used to assessed for peripheral neuropathy Later foot reflexology was administered for the experimental group every one-month interval the investigator was followed same procedures.

Sample Size Calculation

The sample size was calculated assuming 20% improvement in the bio chemical parameter with 30% standard deviation, 90% power with 5% significance level. Predicting a 20% drop out, the sample size was rounded off to 60 patients in each group. (Control, Exp-I and Exp-II)

Ethical consideration:

This present study was approved by the RajaRajeswari Medical College & Hospital, Institutional Ethics Committee (RRMCH-IEC/63/2020-21,Dated: 04.01.2021). Before data collection, each respondent has signed informed consent. Also, the respondents were informed about their voluntary participation, may partially or wholly withdraw during the study, their

identity was anonymous, and no personal identification information was retrieved to ensure confidentiality.

Table 1: Comparison of Control, Experimental 1 and Experimental 2 for homogeneity.

S. No	Variable	Category	Control	Exp 1	Exp 2	□2 test and P value
1	Age (years)	< 34	7	8	0	□2 = 38.650
		35 - 44	13	29	42	P < 0.05
		45 – 54	35	16	18	
		> 55	5	7	0	
2	Gender	Male	17	36	41	□2 = 21.420
		Female	43	24	19	P < 0.05
3	Marital status	Married	60	60	60	NA
		unmarried	0	0	0	
4	Education	Schooling	56	58	60	□2 = 4.138
		Above schooling	4	2	0	P = 0.126
5	Family type	Nuclear	0	0	0	NA
		Joint	60	60	60	
6	Occupation	Farmer	30	48	60	□2 = 45.264
		Labour	25	12	0	P < 0.05
		Official/Business	5	0	0	
7	History of hospitalization	Yes	24	2	25	□2 = 27.743
		No	36	58	35	P < 0.05
n = 60 each NA = Not applicable						

Table 2: Demographic variables of the study population of control, experimental I and II groups

S.No	Variable	Category	Number	Percentage
1	Age (years)	< 34	15	8.3
		35 – 44	84	46.7
		45 – 54	69	38.3
		> 55	12	6.7
2	Gender	Male	94	52.2
		Female	86	47.8
3	Marital status	Married	180	100
		Unmarried	0	0
4	Education	Schooling	174	96.7
		Above schooling	6	3.3
5	Type of family	Nuclear	0	0
		Joint	180	100
6	Occupation	Farmer	138	76.7
		Labour	37	20.5
		Official/Business	5	2.8
7	History of hospitalization	Yes	51	28.3
		No	129	71.7
n = 180				

DISCUSSION:

In general, there is correlation between the peripheral neuropathy with history of Tuberculosis patients. Michigan neuropathy scale act as a parameters for identifying the peripheral neuropathy, with Tuberculosis patients. In this present study all the participants were from rural population and majority of the populations were females.

For experimental group foot reflexology intervention was given. Foot reflexology will help to reduce peripheral neuropathy, especially for drug-induced Tuberculosis patients.

The study revealed that among 180 Tuberculosis patients, age, gender, marital status, family type, occupation and history of hospitalization was not significantly associated, where as education found statistically significant at 0.05 levels. It is observed that the majority of the respondents 46.7% were in the age group of 35-44 years, whereas 38.3% of the respondents in the age group of 45-54years. In relation to age, 52.2% of the respondents were male and 47.8% were females. It is observed that 100% of respondents were from joint families, it is noticed that majority 96.7% of the respondent had schooling, 3.3% had above schooling, It is noticed that majority 76.7% of the respondents were farmer, 20.5% were labor/daily wage, 2.8% had business. It is noticed that majority 28.3% of the respondents had history of hospitalization and 71.7% had no history of hospitalization.

The under diagnosis of PN, especially in primary healthcare in SEA, creates a huge burden of hidden disease. This has a major impact on the quality of life as a result of painful neuropathic symptoms and morbidity due to foot ulceration and amputation, as well as increased mortality. Awareness and a sense of urgency amongst patients and healthcare providers are required, and primary care physicians require access to simple tools to help them diagnose peripheral neuropathy.

The reviewed articles showed that, the present study was supported by Forssbohm, Zwahlen et al 2018 and it was conducted in Germany to determine the demographics of patients with extra pulmonary tuberculosis. Data on 26,302 tuberculosis cases from a national survey carried out during the period 1996–2000 were analysed. The crude proportion of tuberculosis patients with extra pulmonary manifestations was 21.6%. Extra pulmonary tuberculosis was most likely among females, children aged, 15 yrs and persons originating from Africa and Asia. The strength of this association was strongest in the age range 25–64 yrs and less pronounced amongst the oldest patients. The analysis shows important differences, by age, sex and origin, in the likelihood of a tuberculosis patient presenting with extra pulmonary tuberculosis. Since the relative contribution of the foreign born to tuberculosis in low-prevalence countries is rising, extra pulmonary tuberculosis must be taken into account more often in the differential diagnostic work-up of these patients, particularly among those originating from Asia and Africa.

Similarly, another study was supported by Manjusha Sajith, Ansu Thomas et al 2015. A prospective observational study was conducted from August 2014 to April 2015 in Pulmonary Department of Bharati hospital and Research centre, Pune. 112 patients, who came to pulmonary Outpatient department between August 2014 and April 2015, were interviewed. The inclusion criteria of our study was Pulmonary and extra pulmonary TB cases diagnosed on the basis of sputum smear, culture, Chest-radiograph, cytological and histopathological examination receiving anti tubercular drugs therapy. Primary data from each patient was included in Tuberculosis Patient Profile form such as age, gender, marital status, literacy level, annual income, occupational status, social habits and family history of tuberculosis. The most of patients were in the age group of 15-34 years (61.7%). Majority of patients lived in urban area 69.6% and belonged to low socio-economic status (8.9%). In the study 50.9% had PTB, 43.7% had EPTB and 5.4% had Pulmonary TB and Extra Pulmonary TB.

Similarly another study was supported by M N I Mondal , Hoque M. Nazrul et al 2016. A cross-sectional study was conducted at Rajshahi City, Bangladesh. The aims of this study were to identify the knowledge levels of TB and investigate the factors associated with knowledge level among the TB patients in Bangladesh. A total of 384 TB patients were interviewed through a pre tested, structured questionnaire using purposive sampling techniques. Logistic regression analysis was used to evaluate the effects of selected socio-demographic factors on TB knowledge level. The results revealed that pulmonary TB patients had greater knowledge than that of extra-pulmonary patients, and that sex, age, educational status and TB type were significantly associated with knowledge level. In general, males and young adults, ages 21-35, had greater awareness about transmission and prevention of TB than females and adults over 35. Individuals with higher education and urban area patients were comparatively better informed about TB infection.

CONCLUSION:

PN is a common condition, affecting many people with Tuberculosis disease. The cause is likely multifactorial, presenting a complex clinical scenario, but the consequences can be severe and permanent hence a need for vigilance in management. Prevention strategies are key, and all persons being treated for Tuberculosis should receive concomitant pyridoxine supplementation and correction of any modifiable risk factors. All Tuberculosis patients should be routinely screened for PN and have reflexes tested as well as a visual inspection of the feet at each exam. The presence of neuropathic symptoms decreased ankle reflexes, and decreased distal sensations, regardless of distal muscle weakness and atrophy makes the diagnosis of PN likely. Management should focus on halting damage to the nerve although care should be taken not to compromise the Tuberculosis regimen and alleviate symptoms. Counseling and emotional support may be needed in those with severe forms of the disease. Better research is needed to determine ideal management strategies and to

contribute to better health and quality of life for all persons who are survivors of Tuberculosis.

The under diagnosis of PN, especially in primary healthcare in SEA, creates a huge burden of hidden disease. This has a major impact on the quality of life as a result of painful neuropathic symptoms and morbidity due to foot ulceration and amputation, as well as increased mortality. Awareness and a sense of urgency amongst patients and healthcare providers are required, and primary care physicians require access to simple tools to help them diagnose peripheral neuropathy.

Declaration of Conflicting Interest:

The authors have no conflict of interest to declare.

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Authors' Contributions:

All authors made substantial contributions to the conception and design of the study, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content, agreed to submit to the current journal, and gave final approval of the version to be published.

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