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Research Article

PREVENTION OF DISABILITY IN MULTI DRUG TREATED LEPROSY AFFECTED PERSONS THROUGH HOMOEOPATHY IN TWO DISTRICTS OF CHHATTISGARH, INDIA – A PILOT STUDY

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ABSTRACT: A project was undertaken and total 2785 leprosy patients of two districts namely Janjgir-Champa and Raigarh of a state of Chhattisgarh in India, who completed MDT but suffering from loss of sensation in their hand and feet and/or chronic ulcer were registered. Homeopathic medicines were applied and the effects were analyzed by different parameters and documented. Complete regain of sensation was recorded in 63.2% patients and 28.73% showed partial regain whereas no regain of sensation recorded in patients 8.04% and healing of ulcer was recorded in 69% of patients.

Key words: Leprosy, MDT, Sensation loss, Ulcer, Homeopathic treatment.

INTRODUCTION

Leprosy is a leading cause of permanent disability among all communicable diseases (United Nation Report 2009). This disease still continues to be of major concern in developing countries, not only because of the number of people affected by it and their potential for communicating the disease to others, but also because of the occurrence of deformities in a significant proportion of patients.

Development of chronic ulcer is serious outcome of leprosy caused by nerve function impairment. Affliction of peripheral nerve leads to sensory, motor and tropic changes in extremities predisposes and causes ulceration. These ulcers are recognized as grade-II disability for which leprosy affected person becomes crippled physically and psychologically. Early detection of disease particularly the nervous damage is essential for prevention of disability in leprosy. Unfortunately, it is a fact that in spite of best effort early detection could not be made possible. These ulcers usually occur in peripheral organs particularly weight bearing extremities like feet. Among all types disability, plantar ulcer is of serious concern since this attributes maximum disability. There is no specific treatment available for healing of chronic ulcers. The only suggestive treatment

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of ulcers is self-care and rest of the effected part.

As per WHO approved Multi Drug Therapy (MDT) regime (2008), patients are treated on detection of Hansen's disease. The aim of this treatment however confines to kill the pathogens and to check the infection. The patients are declared cured on the basis of absence of pathogens in the host and absence of granuloma in tissue. However, even after released from treatment (RFT) the patients suffer from neuropathy, loss of pigmentation, ulcer and other secondary complications for rest of their life. In many cases after completion of MDT the patients become AFB negative but the bacteria continue to remain in dormant stage in skin, nerve and in certain other locations like muscle which cause relapse of the disease. Studies conducted by different workers suggested that the leprosy affected people remain at risk of neuropathy resulting from immunological reactions caused by *Mycobacterium leprae* antigens during and even after successful anti-leprosy treatment (Rose and Water 1991, Becx-Bleumink and Berhe 1992, Van Brakel and Khawas 1994, Richardus *et al.,* 1996, Schreuder 1998, Croft *et al.,* 2000, Saunderson *et al.,* 2000).

Evidence for the effectiveness of POD interventions in leprosy is limited. There is only one review assessed the effects of corticosteroids for treating nerve damage in leprosy but did not find evidence from randomized controlled trials for a significant long-term effect of steroid therapy in improving either mild sensory nerve function impairment or longstanding nerve function impairment.

A review assessing the effects of interventions for skin damage in leprosy found weak evidence favoring topical Ketanserin over Clioquinol cream or zinc paste and topical phenytoin over saline dressing in ulcer healing. No evidence from randomized controlled trials for the effectiveness of self-care or educational interventions was found. Cost-effectiveness data are even more limited, though the importance of cost-effectiveness analysis has been recognized.

The clinical research undertaken through Homoeopathic medicines so far, recorded a remarkable success in the treatment of planter ulcer and nerve impairment in leprosy cured persons who have been released from Multi Drug therapy and are suffering from different residual effects like chronic ulcers, peripheral anesthesia and other secondary complication (Chakraborty and Chakraborty 2000, Chakraborty *et al.,* 2002). Apart from the clinical evaluation the histo-pathologic study demonstrated that one single homoeopathic medicine has got potentiality to reverse degenerative changes of nerve cells (Chakraborty *et al.,* 2009) and Osteomyelitis (Chakraborty *et al.,* 2013) which is the root cause of associated disabilities in leprosy.

An effort was made to replicate the findings of controlled study in field and a pilot project was undertaken in Chhattisgarh, a leprosy endemic state of India where 2785 leprosy affected persons of two districts namely Raigarh and Janjgir-champa who completed multi-drug therapy and suffering from chronic ulcers and loss of sensation in their hand and feet were treated with a homoeopathic medicine *Mercurius solubilis (Merc sol)*.

MATERIALS AND METHODS

During the period of January 2013 to September 2013, 2785 proven cases of leprosy were identified in different leprosy prevalent

areas of Raigarh and Janjgir Champa, two districts of Chhattisgarh.

Registration of a leprosy affected person (LAP) was done based on case history and clinical sign of a patient with ulcer and/or neuropathy. A patient with history of any of the disease condition like diabetes mellitus, malnutrition, Vitamin B_1 and Vitamin B_6 deficiency, Buerger's disease, Raynaud's disease, atherosclerosis, HIV, Poisoning with heavy metals (*e.g.*, lead, mercury, and arsenic) Lyme disease, peripheral neuropathy due to autoimmune neuritis, neuropathy due viral aetiology, hypothyroidism was not registered under this project. In the case of diabetes mellitus glucose estimation was done.

Cases were grouped into three categories to study the effect of the medicine:

Category 1- Persons residing in Leprosy colonies irrespective of time elapsed since completion of Multi-Drug Therapy (MDT) course.

Category- 2: RFT cases from the community who had completed the MDT for more than one year from the date of start of the project.

Application of medicine

After receiving consent in prescribed format from the patient, on the first day cleaning of the wound/ulcer was done with ordinary soap and water, surgical spirit and calendula Q. Thereafter second day onwards no clearing was done with water. Dressing was done with dry gauge pack daily or every alternate day as was required. *Merc sol* in 200 patency in liquid per *os* once in week was given to all the patients at their door step. In case of any complication the doctor used to monitor dressing and medicine application. Another medicine Calcaria sulph 6X was prescribed in some cases as a supplementary medicine.

After thorough clinical examination and details case study, the selection of medicine was done according to Boerick (1976) and Kent (1978) repertory as followed in a study by Chakraborty *et al.*, (2009). Since in a leprosy patient, the disease symptoms and particular symptoms are found to remain same before or after completion of multi drug therapy so the selection of medicine remains also same.

Reasons for selection of *Merc sol*

[1] It is considered as the king of anti syphilitic medicine.

[2] Every organ and tissue specially the connective tissue, lymphatic system and membrane of the organs was found to be affected by this medicine and it can prevent degenerative changes.

[3] All the patients were very sensitive to heat and cold which was also a common symptom in BL/LL leprosy.

[4] All complaints, especially neuralgic pain reported worse at night.

[4] Profuse oily perspiration day and night.

[5] Tendency to formation of ulcer on tongue and mouth with salivation. This type of symptoms also recorded in BL/LL leprosy.

[6] Bad and violent dreams, sleepless night was one of the important indications, were also recorded as cardinal sign in BL/LL cases.

[7] All these symptoms were the characteristic of syphilitic miasm and as syphilitic miasm showed much symptom similarities with the lepromatous leprosy so for the treatment of BL and LL leprosy Mercurius was selected.

Evaluation Criteria of ulcer and nerve function impairment (NFI) at the time of registration and after onset of treatment at

Scoring

Hand Colour	Approx. Force	Score	Foot Colour	Approx. Force	Score
Blue filament felt	200mg	0	Purple filament felt	2g	0
Purple filament felt	2g	1	Red filament felt	4g	1
Red filament felt	4g	2	Orange filament felt	10g	2
Orange filament felt	10g	3	Pink filament felt	300g	3
Pink filament felt	300g	4	Pink filament not felt		4
Pink filament not felt		5			

Motor nerve function testing was also carried out by Physio-technicians on every patient using modified 5 point MCR scale.

every three months interval.

a. Clinical sigh

b. Size of the ulcer by measuring length and breath

c. Nature of exudates

d. Presence of granulation tissue

e. Nature of the ulcer whether Complicated or simple ulcer

f. Sensory Testing of the anaesthetic hand and feet by Semmes- Weinstein nylon monofilaments and ball pen

The patients were subjected to slit skin smear to observe presence of AFB. Fifty patients were randomly selected and all these patients were subjected for lepromin test, x ray histopathology to study the effect of medicine.

Healing of ulcer was assessed on the basis of following index

i. Measurement of ulcer

Measurement of ulcer was calculated from the greatest length (head to toe) and the greatest width (side to side) using a centimeter ruler. Multiplied these two measurements (length X width) to obtain an estimate of surface area in square centimeters (cm^2).

A centimeter ruler was used and always the same method was practiced each time for measurement of the ulcer.

ii. Type of exudates

Exudate amount: The amount of exudates (drainage) present was estimated after removal of the dressing. The exudate (drainage) was estimated as none, light, moderate, or heavy.

iii. Type of tissue present

Tissue type: This refers to the types of tissue that were present in the wound (ulcer) bed.

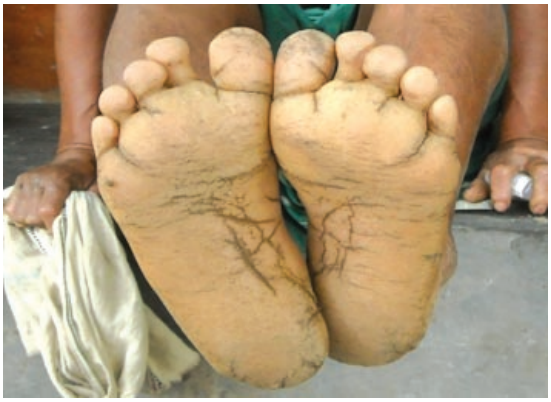

Fig. 1. Feet showing cracks (before treatment).

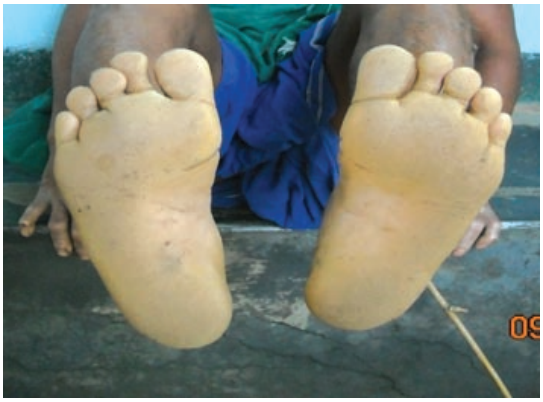

Fig. 2. Cracks disappeared (after treatment).

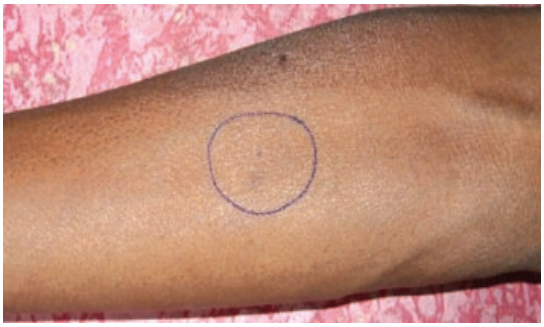

Fig. 3. Lepromin showed negative reaction in a Lepromatous leprosy (LL) case (Before treatment).

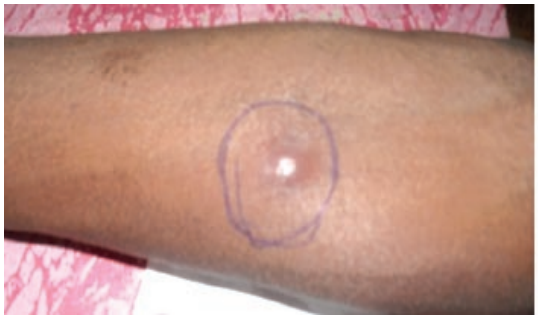

Fig. 4. After treatment with *Mercurius solubilis*, Lepromin showed positive reaction characterized by presence of erythematous nodule (16mm) with ulceration in a Lepromatous leprosy (LL) case.

Scored as a "4" if there was any necrotic tissue present. Scored as a "3" if there was any amount of slough present and necrotic tissue was absent. Scored as a "2" if the wound was clean and contained granulation tissue. A superficial wound that was reepithelializing was scored as a "1." When the wound was found closed, scored as a "0."

4 - Necrotic tissue (eschar): black, brown, or tan tissue that adhered firmly to the wound bed or ulcer edges and found to be either firmer or softer than surrounding skin.

3 - Slough: Yellow or white tissue that adhered to the ulcer bed in strings or thick clumps, or was mucinous.

2 - Granulation tissue: pink or beefy red tissue with a shiny, moist, granular appearance.

1 - Epithelial tissue: for superficial ulcers, new pink or shiny tissue (skin) that grew in from the edges or as islands on the ulcer surface.

0 - Closed/Resurfaced: the wound was completely covered with epithelium (new skin).

Nerve function assessments

A nerve function assessment was carried out

using standard techniques like a) Semmes-Weinstein nylon monofilaments at the time of first appearance before application of the medicine. Sensory nerve function testing of the palms of the hands and soles of the feet was carried out in each patient. Testing was carried out using ball-point pen as described by Jean Watson at twelve standard points on each palm and on eleven points on the soles. On the palm five points were taken as supplied by the ulnar nerve and seven for the median.

Touch sensation was tested using a standard set of colored Semmes–Weinstein monofilaments. The monofilaments used were 200 mg, 2 g, 4 g, 10 g and 300 g. Normal reverence values were 200mg for hand and 10 g for the foot. The test site and scoring methods are given as follows.

Test sites

1. On the ulnar side of the hand:

a.Hypothenar eminence

b.Fifth metacarpal head (MCP 5)

c.Volar surface of the distal phalanx of the little finger

2. On the median side of the hand:

a.Thenar eminence

b.Volar surface of the distal phalanx of the thumb

c.Volar surface of the distal phalanx of the index finger

For the radial cutaneous nerve:

Dorsal on the thumb, at the site of the motor point

3. On the foot:

a.Planter surface of the distal phalanx of the big toe

b.First metatarsal head

c.Fifth metatarsal head

d.Planter surface near lateral border of the foot

e.Lateral border of the foot (just distal from the head of the first metatarsal bone).

Lepromin Test

To assess the immunological status or CMI state in 100 nos randomly selected leprosy patients across the spectrum of disease lepromin test was carried in a using Dharmendra antigen, a suspension of defatted leprosy bacilli first reported by Dharmendra (1985). It was further standardised by bacterial count by Sengupta *et al.*, (1979). This antigen evokes an early as well as late reaction with an intradermal dose of 0.1ml. Early reaction was read after 48 to 72 hours and late reaction after 21 to 28 days of inoculation over the flexor surface of right forearm / induration of 5 mm and above with erythema of 10 mm or more was considered as positive. The early responses were graded as erythematous oedema doubtful E (less than 5 mm) 1 + (5 to 9 mm) 2 + (10 to 14 mm) and 3 + (15 mm and above). Absence of any response was considered negative. Similarly late response graded as lack of evident response negative (-ve) Elevation or infiltration 3 o 4 mm doubtful (±) nodule (5 mm) 1 +, 5 mm to 10 mm, 2 +, 3+ (10 mm above).

Collection of skin biopsy

Using a 6mm punch, skin biopsy in duplicate was taken from edge of the lesion area before onset of treatment and after treatment from 100 randomly selected patients. The biopsies were fixed in 10% buffered formalin, processed in automatic tissue processor (Histokinette, Richert Jung Germany) and embedded in paraffin. Five micron thick paraffin sections were cut and stained with haematoxylin and eosin, modified Fite Faraco method for demonstration of lepra bacilli in tissue sections (Nayak *et al.*, 2003). All the biopsies were given coded number and evaluated under light

microscope by three pathologists independently to avoid any bias on interpretation among pre and post treatment biopsies.

RESULTS AND DISCUSSION

At the end of one year, an evaluation was carried out on 2785 patients. Complete regain of sensation was recorded in 63.2% patients and 28.73% showed partial regain whereas no regain of sensation recorded in 8.04% patients. Healing of ulcer was recorded in 69% of patients. A patient reported with anesthetic feet showing cracked dry condition (Fig.1) became normal with regain of loss of sensation (Fig.2)

Out of skin biopsies taken from fifty patients after registration in twelve cases epidermis was unremarkable. Dermis showed epithelioid cell granulomas involving dermal appendages, blood vessel and nerve fibers. A few Langhans giant cells were seen. Vessel wall appears thick, oedematous with partial occlusion of the lumen. Nerve fibers appear swollen and degenerated. In twenty one cases Epidermis was unremarkable. Dermis shows florid epithelioid cell granulomatous lesions with Langhans' giant cells involving dermal appendages, nerve fibers and perivascular spaces. Nerve fibers appear swollen, degenerated and invaded by inflammatory cells. In seventeen cases epidermis was also found unremarkable. Dermis shows focal collection of lymphocytes and macrophages involving perivascular, periappendageal and perinural spaces. Appendages appear partly atrophic. Nerve fibers appear swollen, edematous and infiltrated by lymphocytes. Vessels are partially occluded.

The skin biopsy taken from the same patients after one year demonstrate normal dermis with appendages. Regeneration of nerve twigs was noticed. Blood vessels appeared normal. Acid Fast Staining failed to demonstrate any presence of Acid fast bacilli. In all cases epidermis was unremarkable. Acid Fast staining failed to demonstrate any presence of Acid fast bacilli.

Slit skin smear done in fifty cases showed AFB +ve in four cases which were found negative after treatment.

Lepromin reaction

All the patients showed no reaction to lepromin testing carried out with standardized Dharmendra antigen before the treatment (Fig.3) whereas same Lepromin testing carried out with standardized Dharmendra antigen evoked both early and late skin reactions (Fig.4) in 43 out of 50 patients (86%) after treatment.

Leprosy still poses major therapeutic challenge to the researchers because the immune system of the host gets adversely affected. Leprosy is a dreaded disease because of the deformities and disabilities (Jopling 1991) caused by immunological reactions against *Mycobacterium leprae* antigens. Hastings *et al.,* 1985). Successful treatment should prevent or heal deformities and disabilities (Palande 1994). Unfortunately people remain at risk became of neuropathy resulting from such reactions during and even after successful multi drug treatment (Van Brakel and Khawas 1994, Richardus *et al.,* 1996, Schreuder 1998, Croft *et al.,* 2000, Saunderson *et al.,* 2000).

Although many countries including India have attained elimination figure of prevalence rate less than 1 per 10,000 populations, the disability of the leprosy affected patients is still remains a major problem. As per the available data 58.85% of new leprosy cases in the world are reported in India. It has been seen that 60% patients have peripheral nerve damage at the time of diagnosis which require treatment with

steroid lasting several months. Even after Multi drug therapy (MDT) long term morbidity possesses major problem. The peripheral neuropathy which is initiated by *Mycobacterium leprae* infection and its accompanying immunologic events, mostly leads to severely debilitating physical, social, and psychological consequences throughout the rest of the life of the affected person.

Nerve damage caused in leprosy affects small dermal nerves and peripheral nerve trunks. Perineural inflammation is a characteristic and hallmark of early leprosy. T cell-mediated inflammation is the main pathological process in leprosy nerve damage. The level of nerve damage in leprosy is high with up to 60% patients having clinically apparent nerve damage at the time of diagnosis; 30% of patents may develop further nerve damage during treatment and 10% may develop new nerve damage after or during MDT. Since the nerve damage is immune mediated, the antibiotics used to treat *M leprae* infection have hardly any effect on the accompanying nerve damage. Thorough scrutiny of available literature confirmed the fact that osteomyelitic changes occur in leprosy appears to be irreversible. There is no effective treatment for healing of planter ulcer and osteomyelitis and rest of the affected part by means of a total-contact cast or bed rest and the vigorous treatment of secondary infection is advised to prevent further destruction of bones and joints. On contrary *Merc sol* found to be effective in treating ulcer and osteomyelitis even in normal working condition without bed rest.

The most remarkable outcome of this treatment are reappearance of normal skin colour and regain of loss of sensation in the lesional areas which was supported by the histopathological findings like reappearance of nerve twigs, sebaceous and sweat glands.

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REFERENCES

Becx-Bleumink M , Berhe D (1992) Occurrence of reaction, their diagnosis and management in leprosy patients treated with multidrug therapy; experience in Leprosy Control Program of the All Africa Leprosy and Rehabilitation Training Centre (ALEWRT) in Ethiopia. Int J Lep 60: 173- 184.

Chakraborty D, Chakraborty T (2000) Treatment of Planter Ulcer in Leprosy. Proceeding of the Asian leprosy Congress 9-13 Nov, 2000, Agra,India.

Chakraborty D, Dutta S, Chakraborty T (2002) Trail of homeopathic medicine in the prevention of disability proceedings of the 16th International leprosy Congress, held in Salvador, Brazil in 4-9th Aug 2002.

Chakraborty D, Chakraborty T, Das S, Sengupta J (2009) A Randomised double blind clinical trial of a homoeopathic medicine in the treatment of trophic ulcer and neuropathy in leprosy. Ind J Res Homeopathy 3(4): 54 - 65.

Chakraborty D, Chakraborty T, Sengupta J (2013) Successful treatment of Osteomyelitis in Leprosy patients by homeopathic medicine. Explor Anim Med Res 3(2):170-177.

Croft RP, Nicholls PG, Richardus JH, Smith WC (2000) Incidence rates of acute nerve function impairment in leprosy: a prospective cohort analysis after 24 months Leprosy Review. 71: 18 – 33.

Dharmendra (1985) The nature of the lepromin reaction. The lepromin test, In: Leprosy Vol.2, Editor Dharmendra, Samant and Company, Bombay. 1037.

Hastings RC, Ridley DS, Job CK (1985) The pathology of leprosy. in Leprosy: medicine in the tropics. Hastings RC(ed),Churchill Livingstone, Edinburgh.

Jopling WH (1991) Leprosy stigma. Lepr Rev 62: 1–12.

Kent JT (1978) Reperatory of the Homoeopathic Materia Medica Indian Publishing Co. New Delhi. 72 - 1303.

Nayak SV, Shivarudrappa AS, Nagarajappa AH, Sacchidanand S, Ahmed SM (2003) Role of modified rapid AFB method in histopathological sections of Hansen's disease. Ind J Dermatol Venereol Leprology 69: 173-174.

Palande DD (1994) Nerve involvement in leprosy – prevention and management of deformities: need for a paradigmshift. Lepr Rev 65: 161–164.

Richardus J H, Finlay KM, Croft RP, Smith WCS (1996) Nerve function impairment in leprosy at diagnosis and at completion of MDT: a retrospective cohort study of 786 patients in Bangladesh. Leprosy Review 67: 297 - 305.

Rose P, Water MFR (1991) Reversal reactions in leprosy and their management. Leprosy Review 62: 113 - 121

Schreuder PA (1998) The occurrence of reactions and impairments in leprosy: experience in the leprosy control program of three provinces in northeastern Thailand 1978 – 1995.III. Neural and other impairments. Int J Leprosy 66: 170 - 181.

Sengupta U, Ramu G, Desikan KV (1979) Assessment of Dharmendra antigen. II. Standardisation of the antigens. Lepr India 51(3): 316-322.

United Nations Enable (2009). The Millennium Development Goals (MDGs) and Disability. http://www.un.org/disabilities/default.asp?id=1470 (accessed June 21, 2015).

Saunderson P, Gabre S, Desta K (2000) The pattern of leprosy related neuropathy in the AMFES patients in Ethipoa: definitions, incidence, risk factors and outcome Leprosy Review 71: 285 - 308.

Van Brakel WH, Khawas IB (1994) Nerve damage in leprosy: epidemiological study of 394 patients in West Nepal – part 1: definition, method and frequencies. Leprosy Review 65 : 204 - 221.

WHO (2008) Enhanced global strategy for further reducing the disease burden due to leprosy (plan period: 2011–2015). New Delhi: World Health Organization Regional Office for South-East Asia.

Boerick W (1976) Pocket manual of homoeopathic meteria medica 9th edn. Seth Dey & Co, Calcutta. 327- 969.

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