

ORIGINAL ARTICLE

A comparative study of homoeopathic medicine – *Sulphur* with the Multidrug therapy in the treatment of paucibacillary leprosy

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ABSTRACT

Background: Substantial number of patients with paucibacillary leprosy may still have active skin lesions at the end of MD treatment because of the continuing immune responses, though this does not denote failure of treatment. A clinical trial was conducted to compare efficacy of a homoeopathic medicine with MDT for the cure of leprosy.

Aim: To compare the effect of a homoeopathic medicine – *Sulphur* with the Multi drug in the treatment of Paucibacillary leprosy according to WHO guidelines.

Materials and Methods: Out of total 90 patients enlisted, 60 confirmed Borderline Tuberculoid (BT) leprosy patients of the age 14 years to less than 60 years were registered under this trial. All the patients were allotted a precoded number, randomly and equally divided in two groups. One group was treated with *Sulphur* in 200 potency in liquid orally once in week for two years and the other group received Paucibacillary (PB) regimen as recommended by WHO. At the end of two years findings were corroborated.

Results: The study showed that MDT therapy (PB regimen) and homoeopathic medicine were found equally effective as histopathology of skin showed no granulomatous lesion. The most significant clinical sign observed in all cases treated with *Sulphur* was reappearance of normal skin colour and regain of loss of sensation of the skin lesion.

Conclusions: MD therapy (PB regimen) and homoeopathic medicine were found equally effective. The patients of paucibacillary leprosy could get rid of the skin symptoms if treatment with *Sulphur* (is also given with MDT).

Keywords: Homoeopathic medicine, Leprosy, *Mycobacterium leprae*, Multidrug therapy, *Sulphur*

INTRODUCTION

Leprosy is a chronic granulomatous disease caused by the bacillus *Mycobacterium leprae* which is still endemic in various parts of the world. It primarily

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affects the skin and peripheral nerves. Clinical presentation depends on the patient's immune status at the time of infection and during the course of the disease.

Due to the implementation of Multidrug Therapy (MDT), the prevalence of the disease has remarkably gone down. Incidence refers to the number of newly detected case in the same period and population (1). Despite an efficient MDT coverage, new case detection rate remains at 4.41 per 10,000 as revealed from a survey conducted in year 2009 in selected endemic districts of two states.^[1] Despite an efficient MDT coverage, new case detection rate remains at 4.41/10,000 as revealed from a survey conducted in the year 2009 in selected endemic districts of two states. However, National Leprosy Eradication Programme report revealed that the new case detection rate has declined further as shown 9.98/100,000 in 2013–14.^[2-4] and a significant percent of these are children.^[4-7] After completion of MDT for 6 month in paucibacillary (PB) leprosy and 1 year in multibacillary (MB) leprosy, clinically most of the patients do not feel cured because of the existence of the symptoms of lesion for a long time. Further viable *M. leprae* have been convincingly detected from such lesions after completion of MDT.^[19,20] Due to this therapy persisters may get an opportunity for relapse^[20,21] and resistant organisms may propagate slowly to infect a host with the primary resistant organism.^[8,9] Studies from India and Mali showed that patients with a very high initial bacterial load (bacterial index more than 4+ on skin smear) have higher relapse rates (4–7/100 person years) and these relapses may occur late (averaging 5 years after treatment).^[10] Therefore, all these factors might be playing an important role in the efficacy reduction of incidence rate in endemic population in India.

In leprosy, the peripheral neuropathy is caused by the *M. leprae* and its accompanying immunologic events. The course and sequelae of the immunologic events often extend many years, may continue long after effective antimicrobial treatment and may have severely debilitating physical, social, and psychological consequences. The immune system of the host gets adversely affected, and available drugs do not promote a symptomatic recovery.

Homoeopathic medicine is known to cure or improve the clinical symptoms of many chronic diseases.^[11-18] This system of medicine has recently been shown

to cure allergic individuals by modulating the immune status.^[20] It has also been shown that these medicines are capable to increase the number of CD4+ T cells in AIDS patient.^[16] In the recent past, a randomized double blind clinical controlled trial conducted on multidrug treated leprosy patients who have been released from treatment has demonstrated remarkable success in the treatment of chronic ulcer and loss of sensation.^[17] It has been reported that the some homoeopathic medicine does possess reversal efficacy of peripheral nerve function in leprosy.^[18,19]

Leprosy still poses major therapeutic challenges. It has been reported that a substantial number of patients with PB leprosy may still have active skin lesions at the end of treatment because of the continuing immune responses though this does not denote failure of treatment.^[21]

A clinical trial was undertaken to prove and compare the efficacy of homoeopathic medicine with MDT for the cure of leprosy.

MATERIALS AND METHODS

In compliance with the WHO guideline on clinical research trial, this trial was registered with Clinical Trial Registry – India (www.ctri.nic.in), Registration No. CTRI/2008/091/000080 Dated – 25.11.2008. This project was approved by the IEC of this Institute and subsequently by the Ministry of Health and Family Welfare, Government of India. Informed written consent was obtained from all the participants included in this study.

A total of 90 patients reported with hypopigmented and hypoesthetic skin lesion with or without neural pain between the period, 'June to August 2007' were enlisted. All these patients were examined thoroughly based on the classification on the Ridley-Jopling scale.^[22] Out of these patients, 60 confirmed borderline tuberculoid (BT) leprosy patients of the age 14 years of age to <60 years were registered under this trial. All the patients were allotted a precoded number, randomly and equally divided into two groups. One group (Group A) was treated with *Sulphur* in 200c potency in liquid *per os* once in the week for 2 years.

The selection of *Sulphur* was based on the cardinal sign and symptoms of shown by Tuberculoid leprosy (TT) and BT leprosy patients, mainly sensory loss

over the lesion area due to damage of peripheral nerve by *M. leprae*. The signs and symptoms simulate the indication of sulfur are listed below.

Indication of Sulphur

1. In leprosy sign and symptoms exhibit through various types of skin patches which are dry with complete loss of sensation. Sensory loss is due to damage of peripheral nerve by *M. leprae*
2. Sulphur is the king of anti-psoric medicine having special affinity for the skin and nervous system
3. Characteristic skin symptoms of Sulphur are very similar to the skin lesion of tuberculoid type of leprosy which are almost dry and scaly
4. Sulphur patient subjected to venous plethora manifested by redness of skin which is similar to erythematous lesion of BT leprosy
5. Sulphur frequently arouses the reactionary power of the organism^[23] and make the organ reactive
6. Skin has symptoms as burning sensation on hands and feet
7. Physically, most of the patients are weak, unhealthy and dirty. Mentally they are always found irritable and forgetful.

Leprosy is the mother of chronic miasm, psora, so an indication of Sulphur prompted to be selected for the treatment of a tuberculoid type of leprosy cases.

The other group (Group B) received PB regimen. This regimen includes Rifampicin 600 mg once monthly and dapsone 100 mg daily for 6 months as recommended by WHO.

After registration all the patients were subjected for detail clinical examination and clinical sign were recorded in details by a dermatologist and physiotherapist. During the study, all the patients were subjected for clinical examination every 6 month interval. Slit skin smear was done in each patient of both the groups at the time of registration and at the end of 2 years.

To assess the immunological status or cell-mediated immune state in leprosy patients across the spectrum of disease, Lepromin test was carried in each patient of both the groups at the time of registration and at the end of 2 years using Dharmendra antigen, a suspension of defatted leprosy bacilli first reported by Dharmendra.^[24] It was further standardized by bacterial count.^[25] This antigen evokes an early as well as late reaction with an intradermal dose of 0.1 ml. Early reaction (Fernandez) was read after 48 to 72 hour and late reaction (Mitsuda) after 21 to 28 days of inoculation over the flexor surface of

the 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 edema doubtful E (<5 mm), 1+ (5–9 mm), 2+ (10–14 mm) and 3+ (15 mm and above). The 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, and 2+, 10 mm above, 3+.

For the histopathologic study, using a 6 mm punch, skin biopsy was taken from the edge of the lesional area before the onset of treatment and at the end of treatment. The biopsies were fixed in 10% buffered formalin and processed. Five micron thick paraffin sections were cut and stained with hematoxylin and eosin, modified Fite-Faraco method for demonstration of lepra bacilli in tissue sections.^[26] All the biopsies were given coded number and evaluated under a light microscope by three pathologists independently to avoid any bias on interpretation among pre- and post-treatment biopsies.

At the end of 2 years, on completion of treatment the code allotted to the patients were disclosed to the investigators and assessor for corroborating the findings of histopathology and immunology study.

All the patient were subjected to follow-up study for another period of 2 years.

RESULTS AND DISCUSSION

Clinical Signs

The clinical signs of all the patients are presented in Table 1.

Group A (before treatment)

Single large, well defined hypopigmented, hypoesthetic dry skin lesion was noticed in almost all the patients suggestive of BT leprosy. Single well defined reddish coloured patch with elevated margin present in hand with complete loss of sensation was recorded in some patients [Figure 1a]. The appearance of the patients was, in general, dull and psychological depression was noted in most of the cases [Figure 2a]. More than one lesion was found in 11 cases. These well-defined hypopigmented, dry lesions were found on both hand and/or feet with the complete loss of sensation, perspiration, and hairs. In 6 cases, no nerve involvement was noticed.

Table I: Comparative study between two groups (TT/BT) treated with a homeopathic medicine and MDT in respect of reappearance of normal skin colour

Patient treated with Sulphur (Gr - A)			Patient treated with MDT (PB) (Gr - B)				
Code	Type	Regain of normal skin colour	Code	Type	Regain of normal skin colour		
		Before treatment	After treatment		Before treatment	After treatment	
112/08	BT	Hypopigmented	Normal	101/08	BT	Hypopigmented	No change
118/08	BT	Dry, Hypopigmented	Normal	129/08	BT	Hypopigmented	No change
127/08	BT	Dry, Hypopigmented	Normal	102/08	BT	Dry, Hypopigmented	Disappeared
130/08	BT	Well marked Hypopigmented	Area decreased	105/08	BT	Dry, Hypopigmented	No change
131/08	BT	Dry, Hypopigmented	Normal	107/08	BT	Dry, Hypopigmented	No change
133/08	BT	Hypopigmented	Normal	108/08	BT	Well marked	Area decreased
136/08	BT	Hypopigmented	Normal	109/08	BT	Well marked copper coloured	No change
145/08	BT	Erythromatous with elevated margin	Normal	114/08	BT	Dry, Hypopigmented	No change
146/08	BT	Well marked, copper coloured	No change	120/08	BT	Hypopigmented	No change
152/08	BT	Dry, Hypopigmented	Normal	124/08	BT	Dry, Hypopigmented	No change
159/08	BT	Erythromatous with elevated margin	Normal	123/08	BT	Dry, Hypopigmented	No change
283/08	BT	Dry, Hypopigmented	Normal	140/08	BT	Dry, Hypopigmented	No change
168/08	BT	Dry, Hypopigmented	Normal	143/08	BT	Dry, Hypopigmented	No change
183/08	BT	Copper coloured	Normal	151/08	BT	Dry, Hypopigmented	No change
190/08	BT	Dry, Hypopigmented patch	Normal	156/08	BT	Erythromatous with elevated margin	No change
191/08	BT	Dry, Hypopigmented patch	Normal	157/08	BT	Erythromatous with elevated margin	No change
113/08	BT	Blackish patch	Normal	163/08	BT	Dry, Hypopigmented	New Blister developed
144/08	BT	Hypopigmented	Normal	166/08	BT	Copper coloured patch	No change
202/08	BT	Dry, Hypopigmented	Normal	170/08	BT	Erythromatous patch	No change
209/08	BT	Hypopigmented	Normal	176/08	BT	Erythromatous with elevated margin	No change
211/08	BT	Hypopigmented	Normal	185/08	BT	Dry, Hypopigmented patch	No change
221/08	BT	Dry, Hypopigmented	Normal	193/08	BT	Hypopigmented	No change
232/08	BT	Hypopigmented	Normal	177/08	BT	Erythromatous patch	Disappear
237/08	BT	Dry, Hypopigmented	Normal	204/08	BT	Dry, Hypopigmented	No change
240/08	BT	Hypopigmented	Normal	216/08	BT	Dry, Hypopigmented	No change
246/08	BT	Dry, Hypopigmented	Normal	225/08	BT	Dry, Hypopigmented	No change
128/08	BT	Erythromatous with elevated margin	Normal	230/08	BT	Dry, Hypopigmented	No change
139/08	BT	Dry, Hypopigmented	Normal	235/08	BT	Dry, Hypopigmented	No change
138/08	BT	Well marked dry, Hypopigmented patch	Normal	241/08	BT	Dry, Hypopigmented	Disappeared
117/08	BT	Dry, Hypopigmented	Normal	245/08	BT	Dry, Hypopigmented	No change

TT: Tuberculoid leprosy, BT: Borderline Tuberculoid, MDT: Multidrug Therapy, PB: Paucibacillary

Group A (after treatment)

After treatment, in 96.6% cases, the hypopigmented patch disappeared. The reappearance of normal skin color was gradual. Initially, at the end of 6 months the lesion was found to be less shiny. After 1 year of treatment all the hypopigmented patches nearly disappeared. At the end of 1½ years, the skin regained its normal texture and color and was found almost normal [Figure 1b]. Regain of sensation was recorded. Touch sensation was recovered first, and then pain and gradually heat and cold. The appearance was normal and no dullness or psychological depression was noted [Figure 2b]. The condition of the nerve was normal in all the cases except 2 cases.

Group B (before treatment)

The subjects of this group showed clinical signs identical to Group A. Single well defined reddish colored patch on hand, feet or any other part of the body was recorded with complete loss of sensation [Figure 3a]. Multiple hypopigmented patches were also found to be present on hand, feet and face with loss of sensation. Muscular atrophy was noticed in 1 case. Involvement of single nerve was recorded in 3 cases.

Group B (after treatment)

The patients with single well defined reddish colored patch changed into the ill-defined patch with no regain of sensation. Muscular atrophy



Figure 1: (a) A borderline tuberculoid case with well defined erythematous hypo-aesthetic patches present on left hand (wrist). Shape is irregular with elevated margin. (b) After one and half year of homoeopathic treatment of a Boderline Tuberculoid case the lesion disappeared



Figure 2: (a) A borderline tuberculoid case with psychological depression. (b) After completion of homoeopathic treatment the lesion completely disappeared and the patient was found to get rid off psychological depression



Figure 3: (a) A case of borderline tuberculoid leprosy showing well defined erythematous hypo-aesthetic lesion in hand. (b) Photograph showing ill-defined erythematous hypo-aesthetic lesion in hand of a Boderline Tuberculoid leprosy patient after two year of treatment with PB regimen of Multi drug

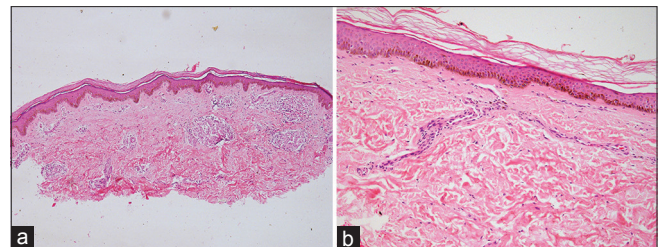


Figure 4: (a) Low power view of skin biopsy of a BT patient showing presence of multiple granuloma in the subepidermal region (H and E). (b) Extensive reduction in granuloma size. Cellular collection in the form of a streak and absence of infiltration around skin appendages are noted (H and E)

was present in 1 case. In 6.6% cases, patch almost disappeared without regain of sensation. In 94.6% cases, the hypopigmented, macular, hypoesthetic lesion remained unchanged. The clinical examination undertaken at 6 months period of interval demonstrated no change in the character of the lesion in 94.6% cases [Figure 3b]. No sweating was noted in the lesional area. Single nerve involvement was recorded in 3 cases as recorded at the time of registration.

Comparison between Groups A and B in respect of regain of sensation and reappearance of normal skin color are presented in graphical form in Graph 1 and Graph 2.

Slit skin smear of all patients of both the groups showed the absence of any organism before and after the treatment.

Histopathology

Group A (before treatment)

Epidermis unremarkable. Dermis showed a focal collection of lymphocytes and macrophages involving perivascular, periappendageal, and perineural spaces. Focal collection of epithelioid cell granulomas with giant cell formation was noticed in the subepidermal region [Figure 4a]. Sweat gland and sebaceous glands were found atrophied in many cases. Nerve fibers appeared swollen and infiltrated by lymphocytes in some cases.

Group A (after treatment)

In general, epidermis appeared unremarkable. Mild collagenization was noticed in the dermis. In dermis extensive reduction in granuloma sizes were recorded [Figure 4b]. No cellular infiltration around skin appendages was noticed. In some cases cellular collection in the form of a streak noted.

After 2 years, epidermis appeared unremarkable. Dermis showed normal appearance with dermal

appendages and nerve twigs. No nerve infiltration was seen. Sweat glands and hair follicles were well defined. In some cases, mild collagenization was noticed in the dermis.

Group B (before treatment)

Sections showed a picture of hyperkeratosis and acanthosis of the epidermis. Dermis showed perineural, intraneural and periappendageal accumulation of macrophage cell and few epithelioid cells in granuloma formation. In 3 cases, multiple granuloma just below the epidermis and in the deep

dermis were seen. Flattening of the rete pegs of the epidermis was also noted [Figure 5a]. The presence of acid fast bacilli in the form of clusters and globi all throughout the granuloma was recorded in 1 case.

Group B (after treatment)

Most of the tissue section showed mild hyperkeratosis, acanthosis of the epidermis. Dermis showed perivascular, periappendageal and perineural accumulation of lymphocyte and few epithelioid cell in granuloma formation. In other cases, sections showed unremarkable epidermis. In dermis mild perivascular, periappendageal, and perineural lymphocyte accumulation were seen. No granuloma was seen [Figure 5b].

A comparison in respect of two cardinal signs of two study group is presented in Table 1.

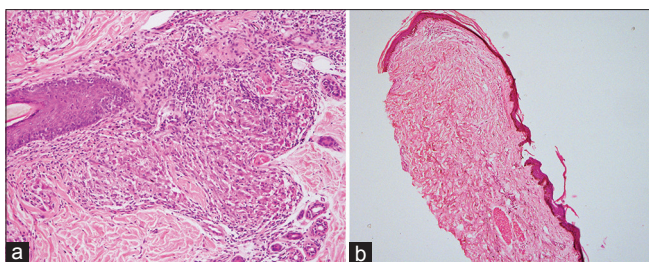


Figure 5: (a) A huge granuloma in the dermis extending upto skin appendages including hair follicle. Essentially a macrophage granuloma interspersed with a few lymphocytes (H and E). (b) Lower power view of the skin section showing resolution of all granuloma (H and E)

Immunology

Lepromin reaction

Before treatment almost all patients of Group A standardized Dharmendra antigen lepromin evoked both early (48–72 h) and late (3–4 weeks) skin reactions.

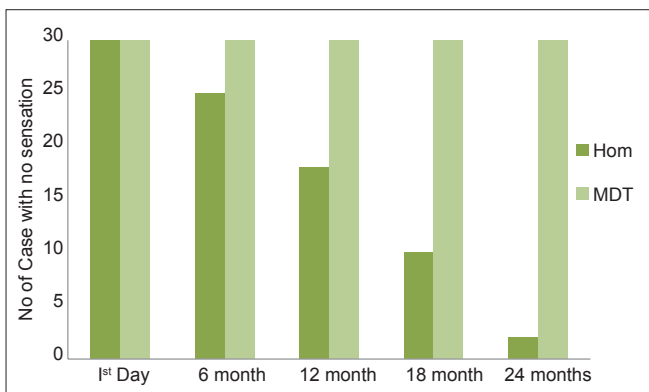
After 2 years in a patient of Group A lepromin reaction was found positive in all cases ranging from 13 mm to 21 mm in early.

Almost all patients of Group B showed a positive reaction to lepromin (both early and late reaction).

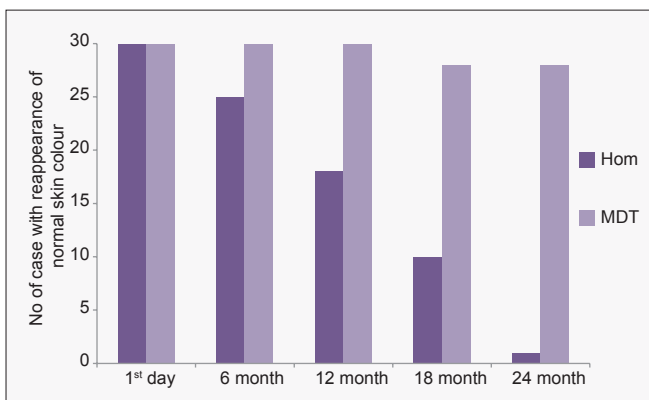
After treatment, all the patients of Group B evoked both early and late reaction to lepromin.

Leprosy still poses a 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.^[27] caused by immunological reactions against *M. leprae* antigens.^[28] Successful treatment should also prevent or heal deformities and disabilities.^[29] Unfortunately, people remain at risk because of neuropathy resulting from such reactions during and even after successful multidrug treatment.^[29-33]

In this study, an attempt was made to compare the efficacy of MDT therapy PB and homoeopathic medicine – *Sulphur* for treatment of BT leprosy with reference to clinical signs, bacterial index, histopathological and immunological study like lepromin reaction. The study showed that MDT



Graph 1: Comparative study of homoeopathy and MDT [TT,BT] in respect of regain of sensation



Graph 2: Comparative study of homoeopathy and MDT [TT,BT] in respect of Reappearance of normal skin colour

therapy (PB regimen) and homoeopathic medicine were found equally effective as histopathology of skin showed no granulomatous lesion. The lepromin status in both MDT regimen and homoeopathic medicine were same. The most significant clinical sign observed in all cases treated with *Sulphur* was reappearance of normal skin color and regain of loss of sensation of the skin lesion.

The finding of this study suggested that the homoeopathic treatment may be adopted to treat fresh cases of PB leprosy. This single remedy in Homoeopathy employed in the treatment of PB leprosy can be augmented with MDT.

The loss of sensation and loss of normal skin color of the lesion are the chief cause of stigma encountered by leprosy affected person. At present, there is no treatment available for regain of sensory loss. In this study a single medicine, *Sulphur* used in the treatment of PB leprosy has been found potential to reverse the loss of sensation and loss of normal skin color of the lesion, in addition, to their bactericidal action.

We would suggest for further follow-up studies that the finding suggestive of regain of sensation in both PB and MB cases should be compared and objectively documented to get the percentage of regain or any improvement by electromyoneurography and starch iodine testing. Due to lack of resources available, our study lacks confirmation of these histopathological findings of nerve regeneration with Mallory trichrome stain and Congo Red stain with polarizing microscopy.

CONCLUSION

In leprosy, after completion of MDT for 6 months in PB leprosy, clinically most of the patients do not feel cured because of the existence of their skin symptoms for a long time. The hypopigmented and hypoesthetic skin lesion is the root cause of social stigma a leprosy patient encounters though out their life.

The patients of PB leprosy could get rid of the skin symptoms if this treatment with *Sulphur* is also given.

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Conflicts of Interest

The authors have obtained appropriate patient consent for the information published in this article.

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मूल लेख: पॉसिबेसिलरी कुष्ठ के उपचार में बहु-औषधि के साथ एक होम्योपैथिक औषधि – सल्फर – का एक तुलनाकारी अध्ययन

पृष्ठभूमि:

पॉसिबेसिलरी कुष्ठ के ऐसे रोगियों की संख्या उल्लेखनीय होती है जिनमें बहु-औषधि (एम डी टी) उपचार के समापन पर भी सक्रिय त्वचा विकृतियां हो सकती हैं। ऐसा सतत प्रतिरक्षा अनुक्रिया के कारण होता है, हालांकि यह उपचार की विफलता निरूपित नहीं करता है। कुष्ठ को पूर्णतः ठीक करने के लिए एमडीटी के साथ एक होम्योपैथिक औषधि की प्रभाविकता की तुलना करने हेतु एक नैदानिक परीक्षण संचालित किया गया।

लक्ष्य:

डब्ल्यूएचओ दिशानिर्देशों के अनुपालन में, पॉसिबेसिलरी कुष्ठ के उपचार में बहु-औषधि के साथ एक होम्योपैथिक औषधि – सल्फर – का एक तुलनाकारी अध्ययन किया गया।

सामग्रियां एवं विधियां:

सूचीबद्ध किए गए कुल 90 रोगियों में से, 14 वर्ष से लेकर 60 वर्ष से कम आयु के ऐसे 60 रोगियों को इस परीक्षण के अंतर्गत पंजीकृत किया गया जिनमें सीमावर्ती ट्यूबरकुलोसिस (बीटी) कुष्ठ की पुष्टि हुई थी। सभी रोगियों को एक पूर्वकोडित संख्या यादृच्छिक रूप से आबंटित कर दो समूहों में बराबर-बराबर बाँट दिया गया। एक समूह का उपचार प्रति सप्ताह एक बार मुख मार्ग से, द्रव में 200 शक्ति वाले सल्फर द्वारा दो वर्षों तक किया गया एवं दूसरे समूह को डब्ल्यूएचओ द्वारा अनुशंसित पॉसिबेसिलरी (पीबी) उपचार योजना प्राप्त हुई। दो वर्ष समाप्त होने पर परिणामों की संपुष्टि की गई।

परिणाम:

अध्ययन ने दर्शाया कि एमडीटी चिकित्सा (पीबी उपचार योजना) एवं होम्योपैथिक औषधि समान रूप से प्रभावी पाई गई क्योंकि त्वचा के उतकविकृतिविज्ञान ने कोई ग्रेनुलोमेटस विकृति नहीं दर्शाई। सल्फर से उपचारित सभी प्रकरणों में प्रेक्षित हुआ सर्वाधिक उल्लेखनीय नैदानिक संकेत त्वचा के सामान्य रंग का पुनः उभरना तथा त्वचा विकृति में संवेदना की पुनः प्राप्ति था।

निष्कर्ष:

एमडीटी चिकित्सा (पीबी उपचार योजना) एवं होम्योपैथिक औषधि समान रूप से प्रभावी पाई गई। यदि एमडीटी के साथ सल्फर का उपचार भी दिया जाए तो पॉसिबेसिलरी कुष्ठ के रोगी त्वचा संबंधी लक्षणों से मुक्ति पा सकते हैं।

Estudio comparativo de un medicamento homeopático, *Sulphur*, con la terapia multifármaco en el tratamiento de la lepra paucibacilar

Fundamentos: Un número considerable de pacientes con lepra paucibacilar sigue teniendo lesiones cutáneas activas tras la terapia multifármaco (TMF), debido a las continuas respuestas inmunitarias, pese a que ello no signifique el fracaso del tratamiento. Se ha realizado un ensayo clínico para comparar la eficacia de un medicamento homeopático con la TMF en la curación de la lepra.

Objetivo: Cumpliendo con las directrices de la OMS, hacer un estudio comparativo de efectos de un medicamento homeopático, *Sulphur*, con la terapia multifármaco en el tratamiento de la lepra paucibacilar.

Materiales y métodos: De un total de 90 pacientes registrados, en este ensayo, se incluyeron 60 pacientes con una lepra tuberculoide borderline (TB) de edades comprendidas entre los 14 y los 59 años. Todos los pacientes fueron asignados a un número precodificado, y aleatorizados y divididos por igual en dos grupos. Un grupo recibió *Sulphur* a la potencia de 200 por vía oral en líquido, una vez a la semana durante dos años, mientras que el otro grupo recibió la pauta paucibacilar (PB) según recomienda la OMS: al final de los dos años, se analizaron los resultados.

Resultados: El estudio mostro que la TMF (pauta PB) y el medicamento homeopático fueron igual de eficaces, dado que la histopatología de la piel no mostró lesiones granulomatosas. El signo clínico más significativo observado en todos los casos tratados con *Sulphur* fue la reaparición de un color cutáneo normal y la recuperación de la sensibilidad perdida de las lesiones de la piel.

Conclusiones: La TMF (pauta PB) y el medicamento homeopático fueron igual de eficaces. Los síntomas cutáneos podrían desaparecer en los pacientes con lepra paucibacilar, si el tratamiento con *Sulphur* también se administra con TMF.