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ORIGINAL ARTICLES

INVESTIGATIONS ON SOME INDIGENOUS DRUGS IN THE TREATMENT OF LEPROSY*

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INTRODUCTION

Sulphones were first used in the treatment of Leprosy about 20 years ago by Faget and associates at the Public Health Service Hospital, Carville, Louisiana. Although, they have gradually replaced the chaulmoogra preparations as standard treatment for leprosy and are still the drug of choice for general use, the earlier optimism regarding their effectiveness has been tempered by experience. At best, Sulphones are bacteriostatic rather than bactericidal (3). They have known shortcomings and so are far from being the ideal drug. The main shortcomings are (1) their slow effect (6) (clinical, bacteriological and histological) in the treatment in some cases and in other (3) relapses have been found to occur after apparent arrest; even (4) bacterial resistance in some cases. Obviously, therefore, the sulphones are not the final goal in the therapy of leprosy.

The search for better therapy has been made more urgent by the great extension of out-patient treatment of millions of leprosy cases all over the world. Unless more effective drugs are discovered, hopes of eradicating leprosy will not be realized (3). Evidence for effectiveness of any treatment, however, can be obtained only by controlled clinical trials. In leprosy, adequate controls are imperative, because its slow natural course tends in activity with occasional exacerbations and remissions. Available measures of clinical and bacteriological changes are far from precise. Acceptable evidence of the value of any method of treatment and of the superiority of one drug

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over another, can be obtained only by study of matched groups of patients, each of sufficient size to permit separation of the frequency of improvement attributable to therapy from that due to natural causes. But inspite of much good work at various centres on several new modern drugs, there is no spectacular progress to record in the the therapy of leprosy (6).

India is regarded to be the pioneer country to give the herbal remedy used in the treatment of leprosy (7), Chaulmoogra or hydnocarpus oil obtained from the seeds of Taraktogenos kurzil (N. India), Hydnocarpus wightiana (S. India) the first and foremost treatment of leprosy till recently (4). But it is not necessary that with this the Indian flora has exhausted for any further contribution in the treatment of the disease. A number of indigenous drugs indicated in the treatment of leprosy are still remaining to be investigated. With the above point in view a planned investigation on some indigenous drugs indicated for treatment of leprosy, in almost all the available authentic classics of Ayurveda (Ancient Indian System of Medicine) viz. Charaka, Sushruta, Vagabhata etc., was carried out at the Institute, as per the procedures laid down in the Ayurvedic system.

MATERIALS AND METHODS

Schedule and Drugs: In the schedule for the conduct of trials with the indigenous drugs, emphasis was laid on two aspects of the Ayurvedic regimen which had to be followed:

(a) The first stage was of preliminary treatment (Poorva–Karma) which was of the nature of preparing the patient for subsequent administration of the drug under trial and

(b) the second stage was of the specific treatment (Pradhana–Karma), the administration of the drug itself. The D. D. S. was taken as the control drug against which the results abtained with the indigenous drugs were compared. In this way four groups were made:

Group I: Preliminary Ayurvedic regimen followed by specific indigenous drugs.

Group II: Preliminary Ayurvedic regimen followed by sulphone.

Group III: Specific indigenous drugs alone without any preliminary Ayurvedic regimen.

Group IV: Sulphone alone without any preliminary Ayurvedic regimen.

Preliminary Ayurvedic Regimen: This regimen was comprised of Snehana (Oleation), Vamana (Emesis) and Virechana (Purgation).

Snehana (Oleation): This process was carried out by the following two standard methods:

(1) Inunction of Tuvaraka Taila (Hydnocarpus oil) mixed with equal parts of Nimba Taila (Azadirachtaindica oil).

(2) Oral administration of medicated and processed Mahatikta ghrita (I) (A compound drug prepared out of herbal medicines and ghee–clarified butter). The Mahatikta ghrita was administered in a gradually increasing dose :—

I	day	morning	2 ounces
II	,,	,,	4 ,,
III	,,	,,	6 ,,
IV	,,	,,	8 ,,
V	,,	,,	10 ,,
VI	,,	,,	12 ,,
VII	,,	,,	14 ,,
		Total	56 ounces within one week.

Both the methods were carried out simultaneously.

Vamana (Emesis). After one day of completing the Snehana process subsequent morning Vamana was introduced. For this, a powder made of equal parts of Patola Patra (Trichosanthes diocia's leaves), Pippalee (Piper longum) and Nimba (Azadiachta indica) bark with Madanphala (Randia dumetorum) was administered orally. The dose differed in individual cases but ranged between 10 to 20 grams for each case in full process. Before starting the process complete intake of the morning, including emetic powder and water which was used as vehicle, was weighed and measured and then administered in each case. In the same way after the completion of the process the total output was also weighed and measured. When the output was found more than what was given as intake then only the process was considered complete and perfect.

Virechana (Purgation). After completion of the Vamana process patients were put in bed for complete rest without any medication for one week. Again the full Snehana process externally and orally was repeated. After completion of the Snehana process patients were not given any medicine for three days. On the fourth day morning, Virechana process was commenced. For this process a powder made of Trivrit (Operculina turpethum) was administered orally. Here also dose differed in individual cases but ranged between 10 to 15 Grams for each case. The process was considered complete and perfect when each case purged at least for 15 times. Maximum purging was twenty five times in few cases. Here again after completion of the process the patients were put in bed for complete rest till one week without any medication.

Thus preliminary Ayurvedic regimen completed within 34 days.

SPECIFIC AYURVEDIC DRUGS

Oral Drugs. (1) Suddha Gandhaka (Purified Sulphur) dose:—8 grains twice a day.
(2) Mahatikta Ghrita (I) dose:—½ ounce twice a day.
(3) Manibhadra Guda (I) (A compound drug prepared out of herbal medicines and sugar) dose:—20 grams once a day, at bed time, twice a week, on Wednesday and Saturday.

External Drug. Nimbadi Lepa (Inunction) (8) (A compound drug prepared out of herbal medicines) dose:—10 Grams of Lepa was applied to the skin, once daily with Takra (Buttermilk).

Source of Drugs. All the drugs used in preliminary Ayurvedic Regimen and specific indigenous drugs were prepared and supplied by the Indian Medical Co-operative Practitioners, Pharmacy and stores Ltd., Lattice Bridge Road, Adyar, Madras 20 South India.

Diet Arrangements. A separate kitchen was maintained for the patients admitted under Ayurvedic Research unit, to enforce strict dietatic restrictions, indicated under Ayurvedic treatment schedule for Leprosy patients.

LIST OF ARTICLES CONTRA–INDICATED

(1) Meat (2) Wine (3) Curd
(4) Milk (5) Gingelly seed (6) Black gram
(7) Radish (8) Red Pumpkin (9) New cereals
(10) Sugarcane and its preparation. (11) Articles like Acidic, Saltish and Ushna (Warm) in action and effect. (12) Heavy articles of diet.
(13) Tamarind (14) Red chillies (15) Condiments.

All the above mentioned articles were not given in diet to the patient under investigation to best of our knowledge. But a few were taking some of the contra–indicated articles surresptitiously and were checked, when it became known.

SELECTION OF PATIENTS

These investigations were started towards the end of 1962. Only untreated advanced Lepromatous cases in good physical condition without any complications such as reactions etc. were selected for the purpose. They were put in blocks of the sanatorium attached with the Institute. The groups who were to undergo the procedure of preliminary Ayurvedic Regimen were admitted in Hospital wards and after the completion of the same they were transfered back to blocks. Other patients remained in the blocks throughout the investigation period and were put in Hospital, only when they had any intercurrent illness which was treated accordingly.

A total of 24 male patients having the above mentioned criteria were selected and included in the investigations, from the out door of the Institute. They were placed in 4 groups, each having 6 patients, as indicated previously in the head 'Schedule and drugs'.

Number of cases, Age, Sex, Duration of the disease in years, Previous history of reaction and treatment is given in Table I; of each group.

RECORDS & LABORATORY INVESTIGATIONS

A record of the initial and follow–up findings in these patients was maintained both according to the Ayurvedic and the Allopathic systems ef medicine.

Records. (1) History and clinical conditions of the cases were recorded in History Sheets.

(2) Charting of clinical picture of cases were done, according to the notations given in 'Notes on Leprosy' by Dr. Dharmendra (2).

(3) Weight of each patient was taken and recorded.

LABORATORY INVESTIGATIONS

(1) Smears were taken from 6 sites and examined with the expression of average degree of positivity in form of a 'Bacteriological Index' (B. I.) by adding the degree of positivity of all the smears and dividing the total by the number of smears examined for future assessment (2). Smears were taken on at least two occasions by the same experienced person, before the beginning of treatment of any group to minimize errors due to the hazards of smearing and to fortuitous changes in concentration of bacilli in the dermis.

(2) Full blood examination, including estimation of the Erythrocyte sedimentation rate by Westerngreen method was performed.

(3) Complete urine and stool examinations were made.

All the above mentioned records and laboratory investigations were repeated at every three months by the same person and methods as they were done before the beginning of the treatment.

CRITERIA FOR ASSESSMENT

The criteria were laid down for the assessment of cases under different gradations such as "Stationary" "Improved" and "Deteriorated". These catagories are defined in the table II.

Assessment of the results of treatment were made on the completion of 6 months (16 cases) at the end of 9 months (12 cases) and at the end of 1 year of treatment (10 cases).

RESULTS

At the end of the year only 10 cases were remaining under the investigation. The other 14 cases discontinued treatment due to one or the other of the following reasons–absconded and discharged on request. In the assessment made at various intervals after treatment there was no indication of any appreciable improvement (clinical and bacteriological) in any of the cases. But most of the cases of group I and III had gained in weight and increase in haemoglobin percent, while most of the cases of group II and IV had lost in weight and decrease in haemoglobin percent.

The findings in the cases of various groups are summarised in the following tables III, IV, V, and VII a, b and c.

Toxicity and complications: No signs of toxicity had developed during the treatment. At the same time no complications like anaemia, neuritis or reaction of any other type had been encountered wnich could be attributed to the preliminary Ayurvedic Regimen and Indigenous drugs.

SUMMARY AND CONCLUSION

Some Indigenous drugs were tried in untreated advanced lepromatous leprosy alone as well as after the preliminary Ayurvedic Regimen. The D. D. S. was taken as the control drug against which the results obtained with the Indigenous drugs were compared after 6 months, 9 months and 1 year of treatment. In the control groups also, D. D. S. was administered alone as well as after preliminary Ayurvedic Regimen. In the assessment made at various intervals after treatment there was no indication of any appreciable improvement (Clinical and Bacteriological) in any of the cases. But most of the cases on Indigenous drugs had gained in weight and increase in haemoglobin percent, with improvement in general condition, while most of the cases on D. D. S. had lost in weight and decrease in haemoglobin percent without any improvement in general condition. There was no untoward effect encountered which could be attributed to the Preliminary Ayurvedic Regimen and indigenous drugs. Therefore it is advocated that the screening of the indigenous drugs, indicated in various classics of of Ayurveda for the treatment of ieprosy should be carried out by planned methods. The drugs which are found to be suitable can be further investigated in various Institutions for confirmation. The Ayurvedic treatment is a comlex one, based on multifarious factors including the basic theories of the Science. Some preliminary preparation of the patient or Poorva–karma of the Sanshodhan (purificatory measures) is an essential pre–requisite for the adoption of any specific therapy or Pradhan–karma of leprosy. Uptil now sufficient stress has not been laid on the evaluation of this particular procedure and other ancilliary measures, therefore, it is necessary to undertake specific investigations on these problems too.

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TABLE I

Nuber of cases, Age, Sex, Duration of the disease in years, Previous history of reaction and treatment; of each Group.

Groups	No. of Cases	Age (In years)	Sex	Duration of the disease (in Yrs.)	Previous history of reaction	Previous history of treatment.
Group I	6	20—45	Male	3—6	No	No
Group II	6	20—44	Male	3—5	No	No
Group III	6	20—40	Male	3—7	No	No
Group IV	6	20—42	Male	3—8	No	No

TABLE II

Criteria for the assessment of cases under treatment.

Clinical Condition	Stationary	Improved	Deteriorated
Nodular & Infiltrative.	No. change	Nodules and thickened areas flattening or flattened, with wrinkling. Freedom from reaction, relief of nerve–pain and eye symptoms and nasal obstruction. Bacteriologically still positive.	Increase in thickening and/or number of patches and nodules, ulceration of nodules, occurrence of repeated reaction. Onset of complications in nerve (nerve–pain) eye (iritis), nose (nasal obstruction). Bacteriologically more highly positive.
Diffuse & Macular	No. change	Almost complete subsidence of erythema, shininess and thickening in the skin, may be with some wrinkling of the skin. Freedom from reaction, relief of nerve–pain and eye symptoms and nasal obstruction. Bacteriologically still positive.	Increase in thickening, number or size of patches, apperance of nodules. Occurrence of repeated reactions, onset of complications in nerves (nerve–pain and tenderness), eye (iritis) and nose (nasal obstruction). Bacteriologically more highly positive.

TABLL III

Condition of cases of group I after 6 months, 9 months and 1 year of traetment with reaction if any and general remarks.

Sl. No.	Case No.	B. I. on Admn.	Reaction	B. I. after 6 months	9 months	1 year	Remarks
1	828/62	2.33	—	2.66	2.80	2.33	1. Weight constant. 2. Hb. increased. 3. Clinically deteriorated.
2	764/62	3.50	—	2.50	3.00	discon-tinued	1. Weight increased by 10 lbs. 2. Hb. increased. 3. Clinically stationary.

TABLE III (contd.)

Sl. No.	Case No.	B. I. on Admn.	Reaction	B. I. after 6 months	9 months	1 year	Remarks
3	827/62	4.00	—	3.00	discon-tinued	—	1. Weight lost 2 lbs. 2. Hb. not changed. 3. Clinically stationary.
4	835/62	3.00	—	3.00	3.00	discon-tinued	1. Weight increased by 8 lbs. 2. Hb. increased. 3. Clinically stationary.
5.	776/62	3.00	—	3.33	discon-tinued	—	1. Weight increased by 13 lbs. 2. Hb. increased. 3. Clinically deteriorated.
6	25/63	2.67	—	discon-tinued	—	—	—

TABLE IV

Condition of cases of group II after 6 months, 9 months and 1 year of treatment with reaction if any and general remarks.

Sl. No.	Case No.	B. I. on admn.	Reaction	B. I. after 6 months	9 months	1 year	Remarks
1	44/63	3.66	Frequent & Acute	3.16	3.33	3.00	1. Weight lost. 2. Hb. decreased 3. Clinically deteriorated. 4. D. D. S. discontinued.
2	72/63	3.00	—	3.00	3.16	2.50	1. Weight lost. 2. Hb. decreased. 3. Clinically improved.
3	73/63	3.16	Fre-quent & Acute	2.50	3.00	2.50	1. Weight lost. 2. Hb. decreased. 3. Clinically deteriorated. 4. D. D. S. discontinued.
4	41/63	3.16	—	discon-tinued	—	—	—
5	77/63	3.30	First Reaction	discon-tinued	—	—	—
6	78/63	3.30	First Reaction	discon-tinued	—	—	—

TABLE V

Condition of cases of group III after 6 months, 9 months and 1 year of treatment with reaction if any and general remarks.

Sl. No.	Case No.	B I. on Admn.	Reaction	6 months	B I. after 9 months	1 year	Remarks.
1.	4/63	3.00	—	3.16	3.00	2.80	1. Weight constant 2. Hb. increased. 3. Clinically deteriorated.
2	5/63	3.00	Once & Mild (after vaccination)	3.00	2.66	3.00	1. Weigh lost. 2. Hb. constant. 3. Clinically deteriorated.
3	16/63	3.33	—	3.16	2.66	3.16	1. Weight increased by 4 lbs. 2. Hb. increased. 3. Clinically deteriorated.
4	15/63	3.16	—	3.00	discontinued.	—	1. Weight increased by 4 lbs. 2. Hb. increased. 3. Clinically stationary.
5	6/63	3.16	—	4.00	discontinued.	—	1. Weight lost. 2. Hb. decreased. 3. Clinicall deteriorated.
6	14/63	2.53	Once & Acute.	discontinued.	—	—	—

TABLE VI

Condition of cases of group IV after 6 months, 9 months and 1 year of treatment with reaction if any and general remarks.

Sl. No.	Case No.	B. I. on Admn.	Reaction	B. I. after 6 months	9 months	1 year	Remarks
1	93/63	3.50	—	3.16	3.33	3.23	1. Weight constant. 2. Hb. decreased. 3. Clinically improved.
2	122/63	3.66	—	3.00	3.16	3.10	1. Weight increased. 2. Hb. increased. 3. Clinically improved.
3	235/63	3.00	—	3.00	2.60	2.60	1. Weight lost. 2. Hb. increased. 3. Clinically improved.
4	240/63	3.00	—	discontinued.	—	—	—
5	99/63	3.33	—	discontinued.	—	—	—
6	119/63	3.16	—	discontinued.	—	—	—

TABLE VII

Summary of Assessment of cases belonging to different groups after 6 months (A), 9 months (B) and 1 year (C).

(A)

Groups	Total No. of cases	Clinical			Bacteriological		
		Stationary	Improved	Deterioroted	Stationary	Improved	Deteriorated
Group I	5	3	..	2	1	2	2
Group II	3	..	1	2	1	2	..
Group III	5	1	..	4	1	2	2
Group IV	3	..	3	..	1	2	..

(B)

Group I	3	2	..	1	1	1	1
Group II	3	..	1	2	..	2	1
Group III	3	..	..	3	1	2	2
Group IV	3	..	3	..	..	3	..

(C)

Group I	1	..	..	1	1	..	..
Group II	3	..	1	2	..	3	..
Group III	3	..	..	3	1	2	..
Group IV	3	..	3	..	..	3	..

REFERENCES

1. Das, Govind; Bhaishajyaratnawali, Published by Chawkhambha Sanskrit Pustakalaya, Banaras 1,1951, Page 218,618–640, Verses 1–4.77.78,243–249.
2. Dharmendra, Notes on Leprosy, Published by the Ministry of Health, Government of India; New Delhi, 1960, Page 176–181.
3. Guinto, Ricardo, S; Talentino, Jose G.; and Daull, James A, Clinical Evaluation studies of the Leonard Wood Memorial, Internat. J. Leprosy. Vol. 32, Page 160, No. 2 April–June, 1964.
4. Muir, E., Leprosy Diagnosis, Treatment And Prevention (Sixth Edition), Published by the Indian Council of the British Empire Leprosy Relief Association, Delhi and Simla, India, Page 116 (Chap. XVII), 1938.
5. Ojha, Divakar, Leprosy in Ayurveda, Nagarjuna, Aug. 1964, Page 935–945.
6. Reports of the Round Tables and Panels of the VIII International Congress of Leprology, Panel on Therapy Report, Leprosy In India, Vol. XXXVI, No. 2, Page 129, 130, April, 1964.
7. Tripathi, S. N.; Chaturvedi, G. N.; Dube, G. P. 'Effect of Achyranthes Aspera in The Treatment of Leprosy', Journal of Medical Sciences, B. H. U., Vol. IV. No. 2, July 1963.
8. Vagabhata; Astangahridayam, Chikitsita Sthanam, Kushtha Chikitsitam Adhayayah 19, verses 65–66.