

Apamarga (*Achyranthes aspera*) in the Treatment of Lepromatous Leprosy

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INTRODUCTION

APAMARGA has been used for the treatment of various forms of leprosy (with many claims about its efficacy) by several physicians practising in Indian Medicine. But in addition, a clinical trial of this drug in the form of a decoction of the whole plant, prepared by the methods described in the classics of Ayurveda and administered orally to patients with various types of leprosy, has shown encouraging results in reaction and the quiescent stage of the disease (Tripathi *et al.*, 1963)⁵. In order to obtain additional data on this indigenous drug several more scientific investigations were planned and a report of the preliminary observations of the drug in the management of reactions in leprosy has already been published (Ojha *et al.*, 1966)³, confirming the effective role of the drug in the therapy of reactions in leprosy particularly in the subacute and the mild type. The present paper includes another aspect of the same study.

METHODS AND MATERIALS

Thirty-six advanced, infiltrated and nodular type lepromatous patients who had had no previous treatment (as revealed by their histories) were selected and included in this trial from the leprosy clinic of S.S. Hospital, Varanasi. When selecting the patients factors such as age, sex, weight and the stage of the disease were duly considered so as to obtain almost identical patients. These patients were equally assigned to the different therapy groups at random.



Achyranthes aspera (Apamarga)
(Under trial for Leprosy).

FIG. 1

A twig of plant *Achyranthes aspera* (Apamarga) with flowering top. The decoction of this whole plant was used for the treatment of lepromatous leprosy.

The groups were given: (A) the decoction of the whole plant of *Achyranthes aspera* (Fig. 1); (B) Diaminodiphenyl sulphone (DDS-Dapsone); (C) the decoction of the whole plant of *Achyranthes aspera* as well as Diaminodiphenyl sulphone.

TABLE I
Criteria for the Assessment of Patients under Treatment

<i>Clinical Condition</i>	<i>Stationary</i>	<i>Improved</i>	<i>Deteriorated</i>
Nodular and 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 the thickening and/or number of patches and nodules, ulceration of nodules, occurrence of repeated reactions. Onset of complications in nerves (nerve-pain), eye (iritis) and nose (nasal obstruction). Bacteriologically more high positive.
Diffuse and 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, appearance of nodules, occurrence of repeated reactions. Onset of complications in nerves (nerve-pain and tenderness), eye (iritis) and nose (nasal obstruction). Bacteriologically more high positive.

The decoction of the whole plant of *Achyranthes aspera* was prepared by taking 1 part of the dry drug and 8 parts of water. The whole was heated till it was reduced to a quarter. This decoction was administered orally at a dose of 1 oz. twice daily. The so-called ideal drug of leprosy, DDS, was administered orally as a control drug, starting on a dosage of 10 mg. daily, and increasing by 10 mg. every week to a maximum of 100 mg. daily for 6 days a week. The patients on the combined treatment received full doses of each drug. The decoction was also administered only 6 days a week from the very week from which DDS was given only 6 days a week.

Records of history, clinical condition, weight, haematological examinations including erythrocyte sedimentation rate, urinalysis, stool examination, bacterial status and their successive progress reports were maintained. For keeping the records special history sheets were prepared including the body charts. The clinical pictures of the leprosy lesions were depicted with the help of notations suggested by Dharmendra (1960)² on the body charts. Over and above this, clinical photographs were also taken at the beginning and at the time of each assessment.

To make the clinical changes quantitatively clearer the lesion index (L.I.) method of

Davison (1965)¹ was adopted, and for calculating the bacterial index (B.I.) the method of Dharmendra (1960)² was used. These methods were standardised as far as possible. The smears were taken and examined by the same person on each occasion of assessment and from the same skin sites as in the preliminary one.

Clinical and bacterial assessments were carried out every 3 months and finally after one year. The criteria for the assessment of patients under treatment is given in Table I.

RESULTS

The assessments of individuals in one treatment group were compared with those obtained in the other treatment groups. During the course of the study 6 patients were removed from the trial and they had also been excluded from all analysis due to various reasons. Out of these 6 patients one of group 'A' was excluded from the analysis at 3 months as he was not regular in taking the treatment and another patient from the same group 'A' could not report for the second assessment after 6 months. Two patients of Group 'B' were excluded from the analysis as they developed reactions, one after 2 months of the treatment and the other after 5 months. The remaining 2 patients excluded were from the group 'C' although they neither absconded nor developed reactions but were very

TABLE 2
Statistical Results
Assessment of Status of Clinical Indices (Mean of Differences³ ± St. Dev.)

Treatment Groups	No. of Patients	Differences between initial and 12th month			
		Macular Index	Infiltration Index	Nodulation Index	Total Lesions Index
‘A’ Achyranthes aspera	10	−0.2±0.42	−0.7±1.5	−0.5±0.85	−1.6±1.34
‘B’ Dapsone	10	−0.1±0.316	−1.7±0.48	−1.4±0.52	−3.1±0.86
‘C’ Achyranthes aspera + Dapsone	10	−0.3±0.678	−1.7±0.812	−1.8±0.632	−3.7±1.42
Comparisons					
‘A’ v. ‘B’		t<1, P>0.05	t=2.52, P<0.05	t=2.866, P<0.02	t=2.94, P<0.01
‘B’ v. ‘C’		t<1, P>0.05	t<1, P>0.05	t=1.55, P>0.05	t=1.13, P>0.05
‘A’ v. ‘C’		t<1, P>0.05	t=2.46, P<0.05	t=3.89, P<0.01	t=3.39, P<0.01

irregular in taking the decoction, while they were taking DDS regularly. By the end of the trial the number of patients completing assessments was 30, that is, 10 patients in each group, and the results have been based on them.

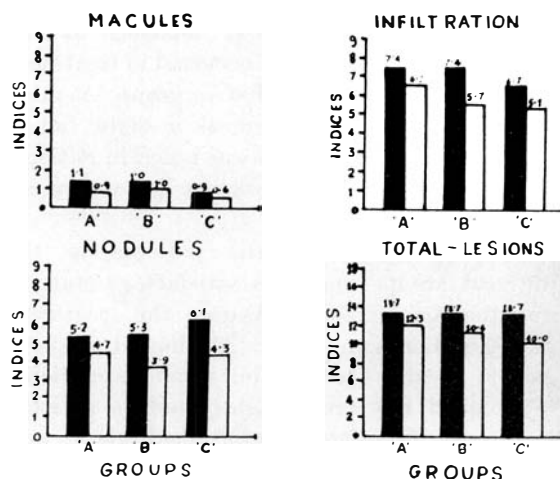
Clinical

All the patients irrespective of group showed clinical improvement of lesser or greater degree. There was a definite indication that the patients of group 'B' made more clinical progress compared to those of group 'A', and the patients of group 'C' made still better clinical progress compared to those of both groups 'A' and 'B' (Fig. 2). The statistical differences in the mean clinical progress between the 3 treatment groups are shown and analysed in Table 2.

Bacterial

All the patients in group 'A' showed no improvement in their bacterial status over the pre-treatment results. Indeed most of them showed a slight deterioration. The patients in groups 'B' and 'C' showed definite improvement in their bacterial indices. The improvement in these 2 groups ('B' and 'C') was not equal as group 'C' showed better improvement compared with group 'B' (Fig. 3). The statistical differences in the mean bacterial indices between the different treatment groups are shown and analysed in Table 3.

FIG. 2
Bar Diagram showing Clinical Assessment in terms of Lesion-Indices (Macules, Infiltration, Nodules and Total-Lesions)



GROUP 'A' = ACHYRANTHES ASPERA
 GROUP 'B' = DAPSONE
 GROUP 'C' = ACHYRANTHES ASPERA + DAPSONE

■ PRE-TREATMENT
 □ POST-TREATMENT

TABLE 3
Statistical Results
Assessment of Status of Bacteriological Indices (Mean \pm St. Dev.)

Treatment Groups	No. of Patients	Period of Therapy					Diff. between initial and 12th month
		Initial	3rd month	6th month	9th month	12th month	
‘A’							
Achyranthes aspera	10	3.125±0.668	3.075±0.725	3.300±0.586	3.395±0.588	3.475±0.571	0.350±0.242
‘B’							
Dapsone	10	2.950±0.725	2.850±0.756	2.575±0.686	2.375±0.737	2.175±0.655	-0.775±0.218
‘C’							
Achyranthes aspera + Dapsone	10	3.000±0.748	2.675±0.678	2.400±0.648	2.075±0.624	1.700±0.583	—1.3±0.258
Comparisons							
‘A’ v. ‘B’		t=0.56, P>0.05	t=0.7, P>0.05	t=2.544, P<0.05	t=3.43, P<0.01	t=4.9, P<0.001	t=10.9, P<0.001
‘B’ v. ‘C’		t=0.15, P>0.05	t=0.55, P>0.05	t=0.604, P>0.05	t=0.98, P>0.05	t=1.71, P>0.05	t=4.95, P<0.001
‘A’ v. ‘C’		t=0.39, P>0.05	t=1.24, P>0.05	t=3.26, P<0.01	t=4.87, P<0.001	t=6.88, P<0.001	t=14.8, P<0.001

General Condition

Haemoglobin: A marked increase in the average haemoglobin level occurred in treatment groups 'A' and 'C', and that in group 'A' more so than in group 'C', whereas a slight fall in average haemoglobin level was noted in patients in group 'B', over the average pre-treatment haemoglobin level.

Weight: Almost all the patients in the different groups were in a satisfactory state of nutrition on admission. During the treatment period patients in group 'A' showed a slight gain in weight. On the other hand the patients in group 'B' lost weight slightly and the patients in group 'C' almost maintained their pre-treatment weight.

Erythrocyte sedimentation rate: All the patients in the 3 treatment groups showed a change in the average E.S.R. levels. The patients in group 'A' showed an increase in their average E.S.R. levels while the patients in groups 'B' and 'C' showed a fall in their average E.S.R. levels. The average change in the way of fall in groups 'B' and 'C' was more marked but almost similar amongst themselves.

FIG. 3
Graph showing Differences in Effect of various Drugs on Bacteriological Status

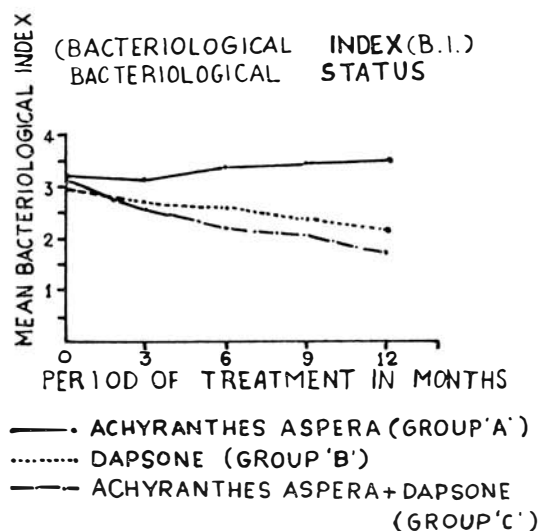


TABLE 4
Statistical Results
Assessment of Progress in General Condition (Mean of Differences \pm St. Dev.)

Treatment Groups	No. of Patients	Differences between initial and 12th month		
		Haemoglobin Grams %	Weight (Kg.)	E.S.R. mms. 1st hour (Westergren)
'A' Achyranthes aspera	10	2.05 \pm 0.86	4.20 \pm 1.04	3.30 \pm 7.33
'B' Dapsone	10	—1.35 \pm 0.94	—2.55 \pm 1.83	—7.70 \pm 38.10
'C' Achyranthes aspera + Dapsone	10	0.85 \pm 1.02	—0.35 \pm 0.479	—0.64 \pm 11.9
Comparisons				
'A' v. 'B'		t = 8.40, P < 0.001	t = 3.23, P < 0.01	t = 0.88, P > 0.05
'B' v. 'C'		t = 5.00, P < 0.001	t = 3.84, P < 0.01	t = 0.56, P > 0.05
'A' v. 'C'		t = 2.87, P < 0.02	t = 13.3, P < 0.001	t = 0.89, P > 0.05

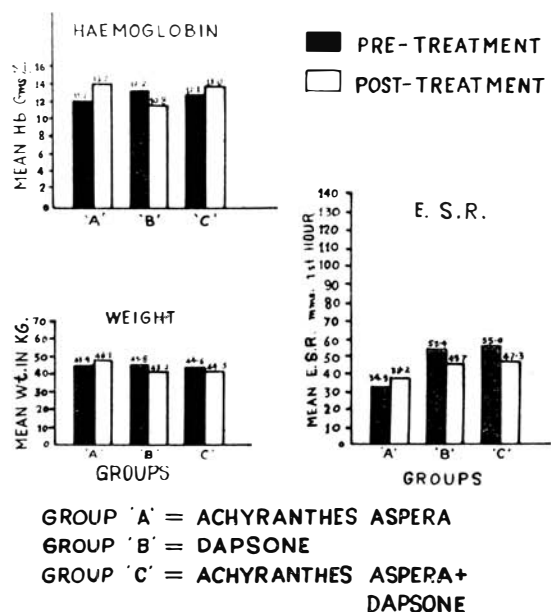
The results concerning haemoglobin, weight and E.S.R. are shown in Fig 4 and the statistical analysis of these data is also given in Table 4.

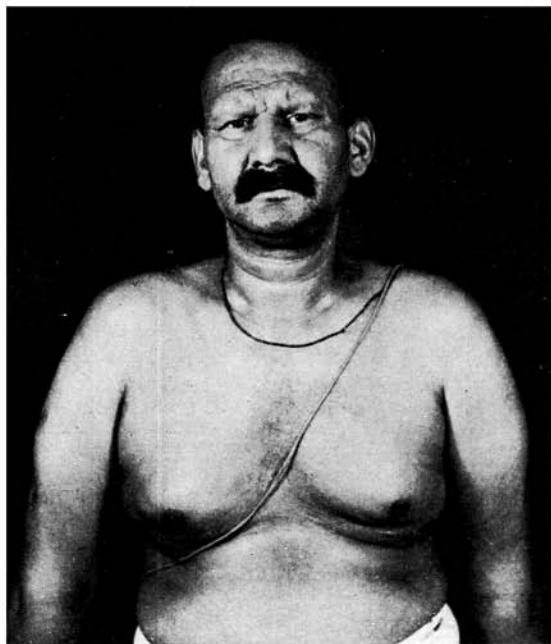
Clinical photographs of patients in the 3 different groups before and after treatment are shown in Figs. 5a and 5b, 6a and 6b, and 7a and 7b.

DISCUSSION

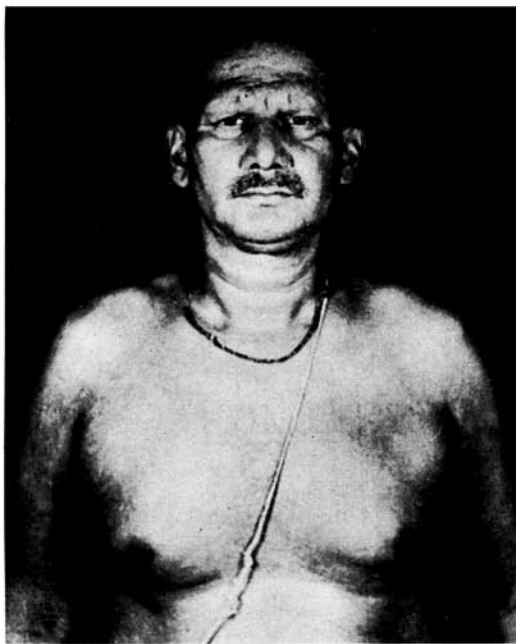
The trial reported here with all its conditions, the standard methods of assessment, i.e., individual clinical progress, the bacterial index, the general health and mean of all these, has revealed differences between the different groups in the response to various treatments. All the patients under study could be considered as improved clinically, consisting of the regression of the diffused infiltration, diminution of the diffused erythema and of the lesions (papules and maculo-papules), flattening of the tubercles and nodules and also in many patients disappearance of the nodules. The clinical progress reveals significant improvement in all 3 treatment groups, but more so in the control group 'B' and still more in the group 'C' which received combined therapy. The marked improvement in the general condition of the patients in group 'A' and group 'C' was noted. With reference to the study of the bacterial index of group 'A' it

FIG. 4
 Bar Diagram showing Status of
 General Condition
 (Haemoglobin (Hb.), Weight (Wt.) and Erythrocyte
 Sedimentation Rate (E.S.R.))





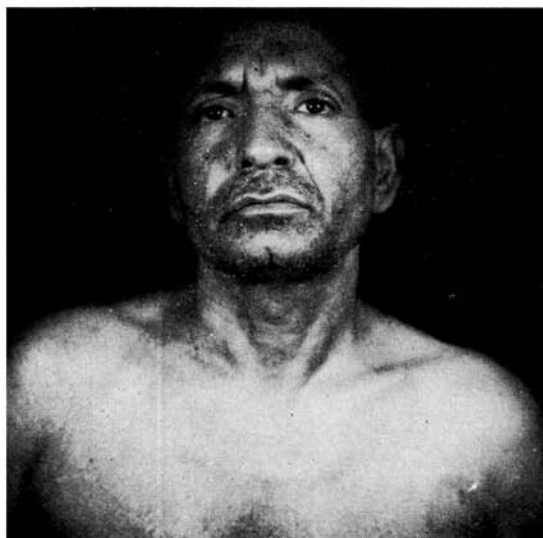
a



b

FIG. 5

Patient with infiltrative lepromatous leprosy. Photograph 'a' was taken before treatment and the patient was put on a decoction of *Achyranthes aspera*. After 12 months of the treatment photograph 'b' was taken. Note that the infiltration has decreased.



a



b

FIG. 6

Another patient with infiltrative lepromatous leprosy. Photograph 'a' was taken before treatment and the patient was put on DDS (Dapsone). After 12 months of the treatment photograph 'b' was taken. Note that the infiltration has decreased.



a



b

FIG. 7

A patient with nodular lepromatous leprosy. Photograph 'a' was taken before treatment and the patient was put on combined therapy (decoction+DDS). After 12 months of the combined treatment photograph 'b' was taken. Note that the number of nodules has decreased, their size has become smaller and they have flattened.

persisted unaltered or showed a slight deterioration. On the contrary in the groups 'B' and 'C' it showed significant improvement, more so in group 'C'. These observations on this controlled study confirm the observation of clinical and general improvement by Tripathi *et al.* (1963)⁵. But observation of the improvement in bacterial index made by them was not supported. In order to assess the possible beneficial influence of a combination of drugs, the decoction was administered concurrently with sulphone therapy. The results obtained have clearly shown the intensity and rapidity of the regressive phenomena as evidenced by clinical, bacterial and general health improvement. This observation was particularly impressive. It is inferred that combined treatment with the decoction and DDS (Dapsone) resulted in a more rapid effective therapy than did DDS alone.

This study has also supported the previous 2 studies, Tripathi *et al.* (1963)⁵ and Ojha *et al.* (1966)³, that the value of the decoction of APAMARGA is effective in the prevention and cure of reactions in leprosy.

The patients in group 'A', in spite of clinical improvement and labelled as bacterially deteriorated, showed a very slight increase of the bacterial index; some persisted unaltered and some others showed fragmented bacilli. This observation may be explained by a statement: 'The bacilloscopic changes did not always proceed in a parallel way with the remarkable clinical results obtained. One of the reasons for this fact could reside in the defective evaluation criteria, since the bacterial index does not allow a satisfactory estimate of the actual numbers of infecting bacilli', made by Opromolla *et al.* (1965)⁴; furthermore they stated that 'the available laboratory methods for evaluating the efficacy of an anti-leprosy treatment are still not very reliable. This is the reason why it seems preferable to rely more on the clinical results obtained and to attribute only a limited value to the bacilloscopic and histopathological data, even if they were favourable in the majority of the patients.'

A further point which deserves a specific mention here is the no reaction phenomena in the decoction-treated groups 'A' and 'C's

and, regarding the tolerance of the drug, it can be clearly said that it was well tolerated as it was given continuously for months without any untoward effect. These findings have also supported the views of Tripathi *et al.* (1963)⁵ and Ojha *et al.* (1966)³.

On the whole, the evaluation of the results obtained by this controlled study indicates that treatment with the decoction of APAMARGA in a dose of 1 oz. twice daily can be considered both well tolerated and effective in reactive as well as in non-reactive states of leprosy.

SUMMARY

A controlled clinical trial is reported of APAMARGA (*Achyranthes aspera*) in the form of a decoction of the whole plant prepared by the methods described in the classics of Ayurveda, administered orally to a good number of patients with the lepromatous type of leprosy for a period of 12 months. The decoction alone was administered to one group of patients and in combination with DDS to another group. DDS alone was administered to a separate similar group of patients.

During the whole treatment period a statistically significant change was noted in the clinical condition, bacterial status and general health. All the patients irrespective of group showed clinical improvement of lesser or greater degree with a definite suggestion that those who received DDS alone made more clinical progress compared with those who received the decoction of APAMARGA alone, and the patients on combined therapy made still better clinical progress in comparison with those patients who received the different drugs separately. The patients who received only the decoction showed no improvement in their bacterial index (B.I.), indeed most of them showed a slight deterioration. The patients on DDS alone and those on a combined therapy of the decoction and DDS showed definite improvement in their bacterial index, still more in those who received both the drugs simultaneously. Improvement in general health was observed in all the patients on the decoction. Those patients who were on DDS alone did not show any improvement in general health.

Clinical and bacterial improvement with betterment in general condition was favoured by combined therapy. Therefore, it is inferred that APAMARGA is effective in the therapy of leprosy. It has been noted that this drug has not produced any toxic manifestation in any patient. If it is administered in conjunction with sulphone (specific anti-leprosy drug) the chances of reaction become limited and the rate of improvement increases.

INFERENCES

1. Decoction of APAMARGA (*Achyranthes aspera*) is clinically effective in the therapy of leprosy.
2. Decoction of APAMARGA potentiates the anti-leprosy action of DDS.
3. Decoction of APAMARGA prevents reactions in leprosy.
4. Decoction of APAMARGA produces no toxic manifestations.

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