

A Clinical Trial of "Ayush 64" (A Coded Antimalarial Medicine) in Cases of Malaria

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Present paper deals with the Clinical trial of 'Ayush 64' on 142 malarial patients that include 55 malarial parasite positive cases. This coded drug have 81% curative effect on Plasmodium vivax (ring and trophozooid). While it is similarly effective on Plasmodium falciparum but with longer therapy with about 90% curative effect. The drug is more effective in ring stage than in Gametocyte stage. In the cases of mixed infection of P. vivax & P. falciparum the curative effect was found to be 75% after longer therapy.

Introduction

Malaria, which at one time was supposed to be under complete control has again become an epidemic. Under the programme of health care organised by the Central Council for Research in Ayurveda and Siddha, CCRAS, (Ministry of Health, Government of India), the tribal pockets and backward areas of Madhya Pradesh have been initiated at the

Regional Research Institute (Ayurveda), Gwalior. Accordingly a 15 days camp from 22 October to 5 November, 1980 was organised during the Tribal Clinical Survey Tour in Shivpuri district in the rural areas where no proper medical aid is available to the inhabitants, viz. Chorpura (Subhashpura), Churailkheda (Indergarh), Sevara, Dhoolagarh, Naya-gaon, Karothra and Bhangarh villages. A survey of the area revealed that a good number of the population was suffering from Sheetpoorvak Jwar and also the incidence of Vishma-jwara was very high in Chorpura area. A total of 142 patients suffering from Vishma-jwara (Malarial fever) were put under trial treatment for the assessment of the coded drug "Ayush 64" supplied by CCRAS.

Material and Method

During the Tribal Clinical surveillance tour, patients with symptoms like (fever) jwar, rigor (sheet, kamp): headache (sirah-

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shoola), backache (*katiprishtha shoola*), bodyache (*angamard*), loss of appetite (*agnimandya*), anorexia (*aruchi*), cough (*kas*), coryza (*pratishyaya*), anamia (*raktalpata*, *pandu*), general debility (*dourabalyata*), vertigo (*bhrama*), and a few cases of enlarged and tender liver/spleen were selected for treatment and assessment with "Ayush 64". The history of *Vishma-jwara* was recorded with temperature at the time of systematic examination of the patients. Thick and thin blood slides were prepared for identification and tests of Malaria Parasite (M.P.). All such patients were diagnosed provisionally as *Vishma-jwara* and on proper identification of blood slides they were finally diagnosed as Malarial cases. At the first instance such type of cases were given "Ayush 64" for two to three days. They were re-examined after three days and were provided further medicines as required but upto a maximum period of nine days. Patients were advised not to take food during the course of treatment and observe complete rest. These under trial patients were regularly followed-up and the improvement in their signs and symptoms, if any, were recorded. M. P. tests were also repeated after three days therapy (first follow-up), after six days therapy (second follow-up) and after nine days therapy (third follow-up).

In all, 142 patients were treated with "Ayush 64" out of which

fiftyfive were diagnosed finally as Malarial cases on the basis of signs and symptoms supported by positive Malaria Parasite test while eighty-seven cases were diagnosed as Malaria cases on the basis of *Lakshana* (symptoms) only as their Malaria Parasite tests were negative.

Criteria of selection of cases

All the suspected cases were diagnosed on the basis of M. P. positive blood films in addition to the following symptoms (*Lakshana*): fever (*jwara*), rigor (*shreet kamp*), headache (*sirhashool*), backache (*Katipristhashool*), bodyache (*angamard*), loss of appetite (*agnimandya*), anorexia (*aruchi*), cough (*kas*), coryza (*pratishyaya*), anaemia (*raktalpata*, *pandu*), general debility (*dourabalya*), vertigo (*bhrama*) and in some cases, enlarged and tender liver and spleen, were also observed. All such cases were selected for the trial of "Ayush 64".

Method of assessment and gradation of response

Assessment was done of the following lines:

1. The cases were subjected for repeated blood film examination and changes, if any, were noted.
2. Symptomatic improvement, if any, in headache, bodyache (*sirhashool* and *angmard*),

feve (*jwar*), anorexia (*aruchi*), lose of appetite (*agnimandya*) cough (*kas*) coryza (*pratishyaya*) etc. were recorded.

3. Improvement in the signs such as temperature, flushed faces (*akrati*), pulse rate (*nadi gati*) and palpable spleen etc. were noted.

The response to "Ayush 64" in cases of *Vishma-jwar* were graded as under:

1. Complete cure:

Patients completely free from all subjective symptoms and objective signs whose blood films were found negative for M. P. after the first or even subsequent follow-ups.

2. Near complete/significant cure:

Patients with near complete relief in subjective symptoms of *jwar*, *sirhashoola*, *angmarda*, *agnimandya*, *sheet*, *kampa* etc. and with similar relief in objective signs temperature, *akrati*, *nadi gati*, palpable spleen and where the blood films examination revealed scanty infection from a previous heavy infection.

3. Partial/Marginal cure:

Patients with only marginal relief in subjective symptoms and objective signs but without any change in the blood film examination for Malaria Parasite which remained positive at the end of the trial.

4. No Response:

No subjective or objective improvement and the blood film remained positive for Malaria Parasite.

5. Drop-out:

Patients for whom follow-up study could not be conducted due to one reason or other.

Duration of Treatment

Tablet "Ayush 64" was administered for 3 to 9 days or as per the requirement of the case.

Dosēs

The doses given to the patients were as follows:

Adult : 2-3 tablets, three times a day with milk or warm water for 3 to 6 days and if necessary, even longer.

Children: 1-2 tablets T. D. S. for 3 to 6 days with milk or warm water.

Observation

142 cases reporting with *jwar sheetpurvak*, *sirhashoola*, *angmarda*, *agnimandya*, *aruchi*, *dourbalyata*, *kas*, *pratishyaya*, *pandu* etc. were observed with "Ayush 64" during the tribal tour to Chorpura area from 22 October-5 November, 1980. Out of these 142 cases fifty-five cases were found to be positive and the other eighty-seven cases were negative for Malaria Parasite but were put to trial with "Ayush 64" on the basis of classical *lakshnas*. The data studied were as under:

Table-2
 Response of "Ayush 64"
 in Cases of Malaria.

S. No. Group	No. of cases	response				
		Cured	Near complete.	Partial	No response	Drop-out
I. Positive for M. P.						
1. <i>Plasmodium vivax</i>	27	22	—	1	1	3
2. <i>Plasmodium falciparum</i>	16	14	—	—	2	—
3. Mixed infection						
<i>P. vivax</i> and <i>P. falciparum</i>	12	9	—	1	2	—
	55	45	—	2	5	3
II. Negative for M.P.	87	63	—	17	—	7
Grand total 142 cases.						

cases showed relief on the first follow-up. On second follow-up examination, two more cases became negative for M. P. and one more cases showed good response at the third follow-up. Only two cases showed no response to the drug (Table IV).

It is therefore obvious that "Ayush 64" showed good response in case of Malaria Parasite *Plasmodium falciparum*, though in comparison to *P. vivax* group. Longer therapy with "Ayush 64" was needed to obtain the desired effect. The results were better and quicker in PFR (*P. falciparum*—Ring stage) than in PFG (*P. falciparum* Gamete) stage of Malaria infection.

Mixed Infection (Group III)

Twelve cases of Malaria suffering from mixed infection (i.e., both *P. vivax* group and *P. falciparum* group) were observed with "Ayush 64".

As such nine cases were cured out of twelve i.e. 75% cured as there was complete relief in subjective symptoms and signs and their blood films were negative for Malaria Parasite.

As is obvious from Table V above, none of the twelve trial cases showed any response to the drug after the first three days and the blood films were still positive for M. P. after three days therapy,

though there had been variable diminution in the subjective symptoms of bodyache, headache, *agnimandya* and *jwar*. After a further course of three days with "Ayush 64" therapy, only six or 50% cases became negative for Malaria Parasite. Three cases became negative after nine days therapy, one was still positive, and two did not report for the third follow-up examination. Three cases who remained positive after the second and third follow-ups were graded under positive or 'No Response'.

It is evident that the drug was least effective in the mixed group and longer treatment was required to obtain the desired effect in these cases.

Toxicity of the Drug

During the course of the present study no toxic effect of the drug "Ayush-64" was observed and its use was free from any side-effect.

Conclusion

During the Mobile Clinical Tour to Chorpura, (a tribal area) 142 cases resported with *jwar sita-purvaka*, *sirahsula*, *angmarda* etc. were subjected to blood film examination for Malaria Parasite. After detailed examination Fifty-five cases were found positive from Malaria Parasite. This comprised of twenty-seven cases of *P. vivax* infection, sixteen cases

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P. falciparum infection and twelve cases of mixed infection both *P. vivax* and *P. falciparum*. Among these fifty-five cases of Malaria, the response to "Ayush 64", was good in forty-five or 80% cases. However seven cases or 13% showed no response to the drug and three cases dropped out from the study.

An attempt was made to analyse the response of "Ayush 64" with reference to the type of Malaria Parasite.

The response was observed best in cases of Malaria Parasite of *P. vivax* as nineteen (70%) at the first follow-up, and five cases at second follow-up were found to be negative for M.P. The results were equally observed in different stages (Ring stage or PVR and Trophozooid stage PVT) of Malaria Parasite.

Fourteen (90%) cases of Malaria Parasite *P. falciparum* showed good response to "Ayush 64" at first follow-up and further two at second follow-up. The results were better and quicker in PFR (*P. falciparum* Ring stage) than PFG (*P. falciparum* Ring stage) than PFG (*P. falciparum* Gamete stage).

Twelve cases of Malaria were found to be suffering from mixed infection. Nine (75%) were cured. But none of these cases

became negative at first follow-up, and only 50% were found negative after six days therapy and further, three cases became negative only after the third follow-up. It was obvious that the drug was least effective in mixed group cases in which longer therapy was required.

It was therefore concluded that "Ayush 64" coded anti-malarial was found to be effective in cases of Malaria infection. The results were best and quickest in *P. vivax* group. The results in *P. falciparum* group were comparable to *vivax* group but slightly longer therapy was needed. The results were better and quicker in ring stage (PFR) than Gamete stage (PFG). The mixed infection with *P. vivax* and *P. falciparum*, showed least effect to "Ayush 64" and longer treatment was required to obtain the desired effect.

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