

Section

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Article

Effectiveness of Medicine *Malaria Off 200*, as Mass Prophylaxis against Malaria in the High-Risk Villages of Shahdol, Madhya Pradesh

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ABSTRACT

Background: Learning from the past experiences, the district health authority Shahdol has planned a mass-prophylactic activity with the Homeopathy Medicine (*Malaria Off 200*) in the selected high-risk villages (above 5 API) in the year 2016. The present paper reports the effectiveness of *Malaria off 200* as mass-prophylactic drug in addition to routine antimalarial activities under NVBDCP in district Shahdol, Madhya Pradesh in year 2016.

Methods: A Homeopathic drug *Malaria Off 200* was used for the mass-prophylaxis of Malaria in high malaria transmission season in selected 28 villages of district Shahdol. The effectiveness of the drug was ascertained as "Reduction of $\geq 20\%$ villages, having more than 2 malaria case in six-month period (July-December 2016) in comparison to the previous year".

Results: Of the 28 villages, seven (25%) reported Malaria case incidence equal to or less than two in six-month period (July-December 2016). In the same time period in previous year 23 (82%) villages reported Malaria case incidence more than two. So, reduction of number of villages with 'biannual Malaria case incidence' rate was 57%.

Conclusion: The short term finding validate the campaign as effective, as per the operational definition of effectiveness coined for the campaign. However, further time series studies with Autoregressive Integrated Moving Average (ARIMA) is recommended for future.

Keywords: Mass-prophylaxis, *Malaria off 200*

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INTRODUCTION

Malaria is one of the oldest known diseases in the history of mankind. Despite of many advances, the disease still remains a cause of widespread poor health in many tropical areas.^[1] In the year 2015 alone, approximately 212 million cases of malaria reported worldwide, however, there is 21% global decrease in incidence between 2010 and 2015. The mortality rate due to malaria has also gone down to 29% between 2010 and 2015.^[2] In India, the prevalence, annual parasite incidence (API) and death due to malaria has decrease since last one and half decades except for the year 2007 when epidemics of malaria took place in North-eastern states of India.^[3] In 2016, there were approximately one million malaria cases reported in Madhya Pradesh, out of them 0.7 million were *Plasmodium falciparum* cases and the

number of deaths reported due to malaria in state were 242.^[2]

Various strategies used for control of malaria under the National Vector Borne Disease Control programme (NVBDCP) are early case Detection and Prompt Treatment (EDPT), measures for vector control i.e.; chemical control, biological control, personal prophylactic measures, community participation, environmental management & Source reduction methods and monitoring and evaluation of the programme.^[4]

Despite of using these strategies, the state has experienced many outbreaks of malaria in year 2015. Out of 93,64,325 blood slides examination for fever cases, 97,200 slides

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turned out positive for malaria parasite i.e. 1.28 Annual Parasite Incidence (API) with Annual blood examination rate (ABER) 12.5. Out of the of the total positives (for malaria), 38.8% tested positive for *Falciparum malaria*. However, death rate has gone down significantly.^[5]

Learning from the past experiences, in the year 2016, the state Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) department planned a *mass-prophylactic* activity with the Homeopathy Medicine (*Malaria Off 200*) in the selected high-risk villages (above 5 API) of 17 districts including Shahdol. It was based on the recommendation by Department of Health & Family Welfare, Madhya Pradesh. The present paper reports the effectiveness of *Malaria off 200* as *mass-prophylactic* drug in addition to routine antimalarial activities under NVBDCP in district Shahdol, Madhya Pradesh in year 2016.

METHODS

General setting:

General setting: Madhya Pradesh is the second largest state and is situated in central India. Shahdol district is located at the eastern part of Madhya Pradesh. It caters 1.47% of total population of state. The sex ratio for the district is 974. The overall literacy rate of the district is 66.7%, however male and female literacy rate is 76% and 57% respectively.^[6] The Schedule Tribe population of district is 44.7% and the population Schedule caste is 8.4%. District Shahdol has five blocks i.e. Beohari, Burhar, Singhpur, Gohparu and Jaisinghnagar. It has two census towns and 844 villages.^[6] [Figure 1]

Specific settings:

The District Health System of Shahdol comprise of one district hospital at Shahdol, one civil hospital at Beohari, seven Community Health centers, 29 rural Primary Health Centers (PHC), one Urban PHC and 226 functional sub health centers. The nearest tertiary health care center is Medical college Jabalpur, which is approximately 200 km from Shahdol.

Selection of villages:

During the preparatory phase of Campaign, the list of villages with high-risk of malaria was obtained by the district AYUSH Officer from the district Malaria Officer to prepare the sampling frame. Those villages, having API more than 5 were considered as high-risk villages for malaria. With the consensus of all stakeholders, initially 95 villages were selected for the present mass-prophylactic campaign, but the result of the present study is based on the reports of 28 villages, from where the complete data was obtained.

Study type:

It was a cross-sectional study of descriptive type. It was done by the record review of secondary data, available at district health system Shahdol.

Study period: From January 2014 to December 2016.

Intervention Protocol for the *mass-prophylaxis* with *Malaria off 200*:

Assigning role and responsibility of stakeholders: Consultation meeting between District Chief Medical and Health Officer (CMHO), District AYUSH Officers, District Malaria Officers, NVBDCP District team with its consultant, Block Medical Officers, Block Programme Managers of all the selected blocks and other officials from state level to

orient about the methodology and micro-plan for the implementation were done. The coordination was also set between the department of women and child development and Department of Health and Family Welfare by the District AYUSH Officer through the district collector with proper meetings at district level.

Training of mid-level managers and peripheral workers:

After the selection of villages for the intervention, District AYUSH Officer ensured the conduction of training to be given to all the staff i.e. MOs, BMO, Malaria Officer, Assisstant Malaria Officer, Malaria Supervisors, Junior Malaria Officer, Surveillance Inspector, Malaria Technical Supervisor, Malaria Worker, ASHA, Block Co-ordinators, MPW (M&F), Multi-Purpose Supervisor, involved under the prophylactic activity as per the directions given from time to time and guidelines as suggested in the AYUSH *Rog Niyanttran Karyakram* before the schedule dates of distribution of drug by the district AYUSH Officer.

All peripheral workers were imparted training through the DAO, AYUSH sector officer, AYUSH MO. During the training, detailed information regarding objective of the intervention, information about drug, consent, possibilities of any adverse drug reaction or any untoward reaction(s) and its reporting, drug delivery, approach for drug administration and counselling etc. were imparted.

Logistic management: The supply of essential items along with *Malaria Off 200* was ensured by the Directorate AYUSH through the Regional and district AYUSH Office. The District AYUSH Officer arranged the distribution of procured medicine to the targeted population with the help of Anganwadi Worker, ASHA, malaria clinics, MPW (Male & Female), Malaria worker under the VBDCP, AYUSH aushdhalaya medical & paramedical personals & all others found suitable including both regular & contractual staff, to the level of Community Health Centres, PHC and SHC. Field supervisors were responsible for monitoring of the drug distribution, consumption and ensuring the un-interrupted drug supplies to peripheral workers for distribution.

Drug dose:

The medicine *Malaria officinalis 200*, 4 to 6 drops in liquid form, was added to Globules No 30 in one-dram phial. This phial containing medicated globules of *Malaria officinalis 200* is sufficient for dose of four persons. Four to six such globules at a time make one dose.

Drug distribution schedule:

For mass awareness of the intervention, pamphlets were distributed with details about the prophylactic activity of the drug. Households were informed about the medicines before and at the time of actual distribution, so that drug consumption is purely voluntary in action.

Peripheral worker visited all the households of their area on fixed days of a week, preferably in morning hours to administer the drugs in their presence. They ensured the drug administration to all family members to the best of their ability. It was the responsibility of the family to ensure drug administration of all left out family members. In this case, all left out persons would approach peripheral worker for their missed dose. Thus, peripheral worker administered drug on weekly basis to all the households. The exclusion criteria were strictly followed in the field. [Box1&2]

Drug dose and schedule: The *Malaria Off 200* is given in total six doses in two rounds. The two rounds were 10 weeks apart. In each round, 3 doses of drug were distributed, at an interval of a week. The rationale behind the gap of 10 weeks

was to administer the drug before another transmission peak of malaria.

The schedule date of first round was 08/07/16, 15/07/16 & 22/07/16 and 30/09/16, 07/10/16 & 14/10/16 for second round. However local authorities were allowed to reschedule the date of distribution due to unavoidable reasons at local level, but to maintain order.

Pamphlets for distribution were also distributed with details about the prophylactic activity of the drug. Households were informed about the medicines before and at the time of actual distribution, so that drug consumption was purely voluntary. Field supervisors are recruited for monitoring of the drug distribution, consumption and ensuring the un-interrupted drug supplies to peripheral workers for distribution.

Box 1: Exclusion criteria

As there was consensus among the experts that there is no adverse effect of the drug, so it can be given to anybody & everybody but from administrative point of view following population were denied of the intervention

- A person who is not a local resident of the village
- Child of age is less than 1 years
- Pregnant & breast-feeding mother
- Person is presently suffering from malaria or under malaria treatment.

Box 2: Recommendations for drug distribution through house to house visit by peripheral workers

- To wash mouth with water before the dose intake.
- Total of four – six globules to be taken in the phial cap and then to be taken in mouth without touching the globules directly.
- Drug needed to be sucked till dissolved rather than swallowed or chewed.
- Medicine not to be taken while betel, tobacco, garlic, *pipermint*, long, *elaichi* or other odorous eatable are in mouth.
- In case person vomits the drug for any reason, then it should be administered again.
- Adverse drug reaction reporting- Instructions were given to all field health volunteers under distribution to stop and discontinue the drug administration in case of any untoward drug reaction or anaphylaxis or allergy. It was also instructed to report reactions immediately for necessary investigations.

Data collection method, schedule and entry:

Predesigned & pretested, paper-based data collection format was designed to obtain the information related to intervention by the peripheral workers. This was compiled for every selected village at subcenter level and then at block & finally at district level in a predesigned data collection in Microsoft Excel sheet then entered in to the Epi Data software (version 2.2.2.183 for analysis, Epi Data Association, Odense, Denmark) for further analysis. The frequency of categorical variables was described in proportion. The data pertaining to village wise target population & population benefitted in selected districts was collected. The monthly confirm malaria cases was collected from January to December for the intervention year (2016) and previous two years (2014 & 2015).

The variables and analysis:

The unit of analysis was the selected villages and the outcome of interest was the *effectiveness* of drug after mass

administration. The definition of *effectiveness* of the drug *Malaria Off 200* as prophylactic agent against Malaria in district was decided as per the consensus among all the stakeholders. The operational definition of effectiveness was ascertained as “Reduction of $\geq 20\%$ villages, having more than two malaria case in six-month period (July-December 2016) in comparison to the previous year”. Considering all these selected villages were highly endemic for malaria as per district Malaria Office i.e. having API five or more, so the reduction of malaria cases to two or less in six months that too in *monsoon* season was significant reduction from the public health point of view.

Data storage and transfer:

The state Malaria department & Department of Practice of Medicine, Government Homeopathic Medical College & Hospital Bhopal being a nodal Office for study was the custodian for the data and ensured that there is restricted strictly authorized access to data. Operationally, the following back up measures was ensured e.g.; Daily back up of data on the excel sheet, consolidated data backup by the Principal Investigator, both on daily basis and weekly basis.

Box 3: Quality assurance in data collection

To ensure quality in data collection, a combination of Methods is adopted and an overview of the same is given below;

- a. Each of the field data collectors was trained systematically by DMO or District AYUSH officer, Shahdol. Peripheral worker was objectively identified & assigned the responsibility.
- b. Strict monitoring mechanism was set up (the monitoring formats used during the training of DMO or District AYUSH officer & other local authorities) and these include:
 - a. Review of daily work done by the co-coordinator
 - b. Review/clarification was obtained from the responsible district health authorities by the coordinator almost on weekly basis.

However, it was not possible to verify the quality of data, as it was obtained by district Malaria office and compiled by the district AYUSH officer.

Ethical consideration:

As this intervention was the part of routine antimalarial activities for the control of Malaria cases under the supervision of office of Chief Medical and Health Officer, Shahdol by the district Malaria department and AYUSH *Malaria Rog Niyantaran intervention*. It was not the part of any trial, so no human ethical consideration was involved however, appropriate programmatic approval was obtained from the competent authorities for the documentation of this intervention. Fever cases detected as positive for malaria were treated or facilitated for the appropriate management, as per standard Malaria Treatment Guidelines.

RESULTS

Present study was the part of joint campaign of *mass-prophylaxis* for Malaria through mass distribution a homeopathic drug *Malaria off 200*. This campaign was the joint venture of the Ministry of AYUSH MP, state cell of NVBDCP, Government Medical Homeopathic College Bhopal, All India Institute of Medical College Bhopal with the collaboration of Office of Chief Medical and Health Offices of selected 17 districts of MP.

The present paper reports the coverage of campaign in district Shahdol. Under this campaign, a total of 95 high endemic villages across all the 5 blocks were selected. Total

population intended to cover under the campaign was 83,409. Since the drug distribution was carried out in the month of July and number of Malaria cases were enumerated through the routine Malaria surveillance programme of the district. The final information related to the campaign was compiled in the month of January 2017. Of the 95, the complete information could have been obtained only for 28 (29%) villages for interpretation. [Table 1] [Figure 2] Out of reported 28 villages under campaign, reduction of Malaria cases to $\geq 20\%$ in six-month duration i.e. July to December 2016 in comparison to same time period of previous year i.e. 2015, was reported in all villages. However, in comparison to year 2014 of same time period, 13(46%) villages reported at least 20% reduction of Malaria cases. [Figure 3]

Table 1: Distribution of block-wise population under the joint AYUSH campaign in district Shahdol, MP, 2016

Block-wise selected villages	Targeted		Covered*		Population
	Block	Villages(n)	Villages(n)	Population	
Burhar	Burhar	27	10	5195	
Singhpur	Singhpur	10	2	1688	
Gohparu	Gohparu	15	4	2521	
Jaisinghnagar	Jaisinghnagar	14	2	441	
Beohari	Beohari	29	10	15662	
Total		95	28	25,507	

Footnote: ##: Population covered under the campaign; \$: Census 2011; #: Targeted population of selected high endemic villages under the campaign; *: Out of total selected 95 villages, data was obtained only for 28 villages, comprising cumulative population of 25,507.

On the basis of operational definition of *effectiveness of the campaign*, of the 28 villages, 7 (25%) reported Malaria case incidence from July-December period, equal to or less than two. In the same time period in previous year 23 (82%) villages reported biannual Malaria case incidence equal to or less than two. So, this apparent reduction of villages with 'biannual Malaria case incidence' rate of 57% is quite suggestive of significant reduction of malaria cases in year 2016. However, the number of villages with ≥ 2 malaria cases was 5 in year 2014. [Figure 4 & 5]

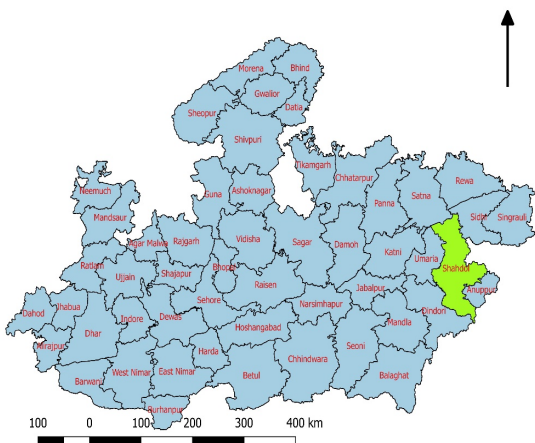


Figure 1: Geographic location of Shahdol, Madhya Pradesh

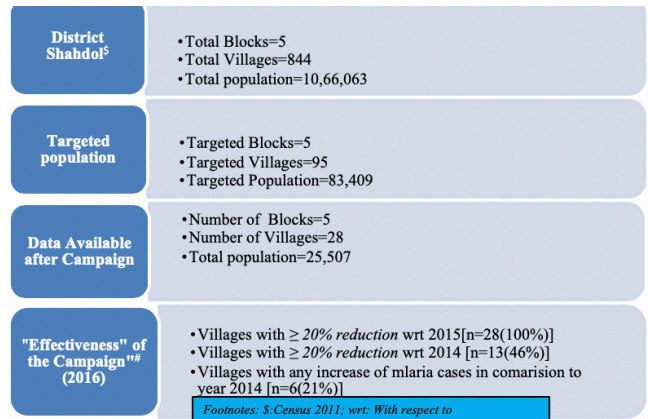


Figure 2: Flow chart depicting sequence of events under the joint AYUSH Malaria campaign, Madhya Pradesh 2016

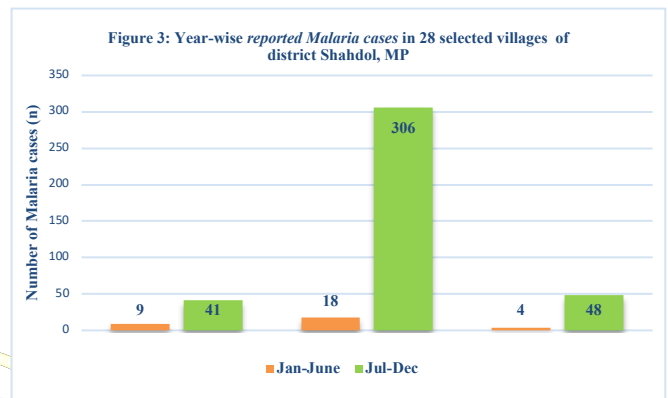


Figure 3: Year-wise reported malaria cases in 28 selected villages of district Shahdol MP

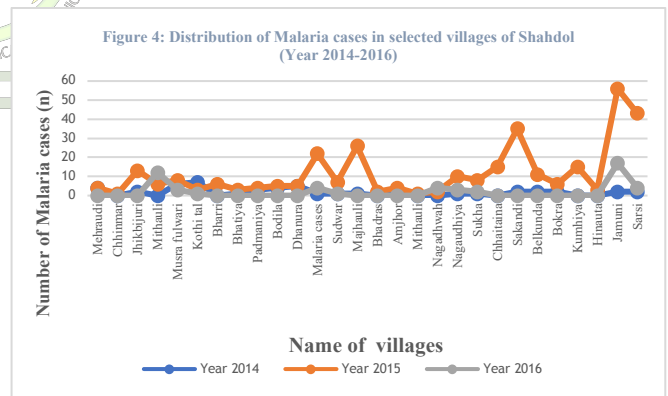


Figure 4: Distribution of Malaria cases in selected villages of Shahdol (2014-16)

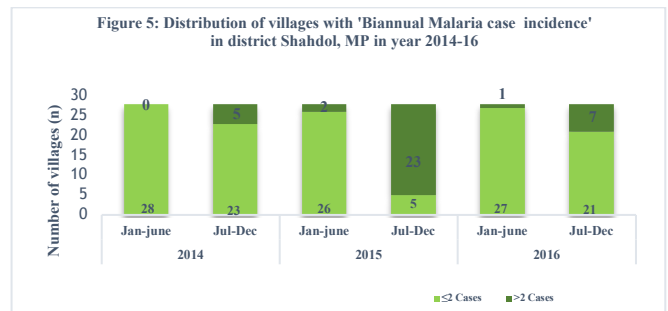


Figure 5: Distribution of villages with 'Biannual Malaria case incidence' in district Shahdol, MP in year 2014-16

DISCUSSION

Present intervention was planned for the prophylaxis activity of malaria in all high endemic villages of district Shahdol. The

primary goal of this campaign was to further strengthen the ongoing antimalarial activities under the district NVBCP.

The present report suggests that after the mass-distribution of *Malaria off 200* in the month of July 2016, there was reduction of 57% villages in six months, who had reported ≥ 2 malaria cases in the same time period in previous year. This short-term finding validates the campaign as *effective* as per the operational definition of effectiveness coined for the campaign. However, comparing to the same time period of year 2014, the number of villages are almost same who had ≥ 2 malaria cases.

The similar evidence is available from neighbouring state Chhattisgarh where another homeopathy drug *Chininum sulphuricum 200* was found effective in prevention of malaria.^[7] There have been field trails to study the comparative efficacy of Quinine and of Synthetic Drugs i.e. Quinacrine and Praequine as mass-praphylaxis for Malaria in transmission season. It suggest that quinine is superior to quinacrine for mass prophylaxis but where close medical supervision is not possible larger doses might not be very safe.^[8] In another field trail, Nivaquine and Rhodopraequine in one group, Chloriguane (Proguanil) and Rhodopraequine in the other was tried but results was inconclusive.^[9] There have been evidence from different quarters of the world for mass-prophylaxis of Malaria but results are either inconclusive, resource consuming and need years of surveillance to reach at conclusions.^[10-15]

Implication: The mass-prophylaxis activity was rolled-out at July 2016. There has been evidence of reduction of Malaria cases in transmission time, in comparison to same time of previous year. This reduction of cases might have been influences by some other factors also like; circannual rhythm of malaria at a specific geography, epidemiological, entomological, environmental & programme level factors can not be undermined. To study the long-term effectiveness of *Malaria off 200*, we recommend future studies should be planned to evaluate the effectiveness of this drug as mass prophylactic agent for malaria through Autoregressive Integrated Moving Average (ARIMA) and Seasonal ARIMA model.^[16-20]

Strengths and limitations: The study had several strengths. First, large sample size of 28 villages and comparing it to the data of last couple of years make the finding robust. Second, we conducted and reported the study in programmatic settings of a tribal dominant district of MP, which has scarce health system resources. Thus, reflecting the realities on the ground. Third, we used internationally accepted guidelines for reporting the study.^[21] We had few limitations also. Inability of data verification, not including other important deterrents in consideration i.e. epidemiological, entomological, environmental & programme level (NVBDCP), incomplete understanding of pharmacodynamics of the drug *Malaria Off 200* & lack of the complete organize system of reporting, adverse effects following campaign are the main limitation in present report.

CONCLUSION

Present mass-prophylactic activity for Malaria by the drug *Malaria-off 200* was found effective as per the operational definition used in present campaign in district Shahdol.

However, this finding is based on routine programme data, so to assess the impact of this mass-prophylaxis activity in the longer term requires more quasi experimental studies with the intention of elimination, especially in high endemic setting like Shahdol. These studies need to address long-term outcomes, potential barriers for community uptake, and contribution to the development of drug resistance.

Funding

The study was conducted under the programme conditions using programme staff. Therefore, no separate budget was required.

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