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**RESEARCH ARTICLE**

# SEVEN ROUNDS OF MASS DRUG ADMINISTRATION WITH DIETHYLCARBAMAZINE AND ALBENDAZOLE TO INTERRUPT WUCHERERIA BANCROFTI INFECTION AND ITS IMPLICATION ON ELIMINATION PARAMETERS IN PUDUCHERRY, SOUTH INDIA

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**ABSTRACT**

Mass drug administration (MDA) with annual single dose of diethylcarbamazine (DEC) in combination with albendazole (ALB) for more than 5 years is the principal tool of lymphatic filariasis (LF) elimination strategy. This study examined the potential of seven rounds of MDA of which initial four rounds with DEC alone and concluding three rounds with DEC plus Albendazole to eliminate Lymphatic filariasis transmitted by Wuchereria bancrofti infection in humans in geographically isolated and non contiguous districts in the Union Territory of Puducherry, South India. Which are bordering endemic districts of neibouring states and administratively same implementation unit..Among the eligible population (>2 years), 49.60to 88.60% received treatment in all seven rounds, After seven rounds of treatment, the microfilaria (Mf) prevalence in treated communities dropped by >90% in two of three sentinel sites in the DEC rounds and all three in the DEC&ALB rounds showed zero Mf prevalence, The results also indicate that DEC&ALB is effective, slightly better than DEC against microfilaraemia. Results from this and other recent operational studies proved that single-dose mass drug administration with DEC and ALBENDAZOLE is very effective at community level to interrupt transmission and proceed further towards verification of antigenemia prevalence as per GELF protocol.



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## INTRODUCTION

Lymphatic Filariasis (LF) is an important health problem in many developing countries. Globally, 1.1 billion people live in known endemic areas (Michael *et al.* 1996) and about one-third of them are infected (Das *et al*. 2000). LF is the second leading cause of permanent and long-term disability (WHO 1995) and undermines the social and economic welfare of the affected people and communities (Ramaiah *et al.* 2000). The World Health Organization launched a global programme to eliminate LF as a public health problem by the year 2020 (Ottesen 2000)/ and in India by 2015. Annual mass treatment with a single dose of diethylcarbamazine (DEC) in combination with albendazole (ALB) is the currently recommended tool of LF elimination programmes (Ottesen 2000). While ALB adds an antifilarial therapeutic effect and beyond filariasis benefits' (Ottesen *et al.* 1999).

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DEC act as the basic and principal antifilarial drugs. Clinical trials demonstrated that a single dose of DEC has an excellent microfilaricidal effect (Cao *et al.* 1997). Based on the efficacy of the drugs and biology of the parasite, it was strategically planned that yearly treatment of communities with antifilarial drugs for 5–6 years has the potential to clear microfilaraemia, drastically reduce the transmission, diminish the adult parasite population and prevent new infections. The cumulative effect is expected to be the elimination of LF. In this study, we present the results of the impact of 7 rounds of Mass Drug administation on microfilaria prevalence in a geographically isolated and administratively united community comprised of rural and urban areas in South India endemic for *Wuchereria bancrofti* transmitted by *Culex quinquefasciatus* and its implication an elimination parameters.

## MATERIALS AND METHODS

### Study area

The Study was carried out in four endemic districts/regions of Puducherry viz Puducherry, Karaikal, Mahe and Yanam in

India to implement the study. These districts are well separated from one another and constituted separate transmission zones. The population of the study areas ranged from 41934 in yanam to 9,46,600,in Puducherry and lives mainly from agriculture and business. LF is a major public health problem, as are nutritional disorders and intestinal helminth infection. There had been organized filarial control programme since 1967, for decades anti-larval operation to reduce man-vector contact and anti-parasitic measures aimed at reducing parasite load in the community were followed. Filaria clinics and private medical practitioners are the treatment points for the filariasis patients.

**Puducherry**

Puducherry is located at 11.45 degree to 12.15 degree north latitude and 79.35 degree to 80.0 degree east longitude on the coromandel coast of peninsular India. The climate is characterized by humid summer, rainy days and a relatively cool season. Hence the climate is referred to as dissymmetric type (Rajagopalan and Das, 1987). The UT of puducherry has an areas of 492 sp.kms and a population of 946,600 according to 2011 census. Puducherry is known to be endemic for filariasis since 1957 (Nair, 1960). The initial endemicity rate was 13.6% (NICD, 1967). Karaikal, is one of the four regions of the UT of Puducherry in India. Karaikal town (about 16 km north of Nagappattinam and 12km south of Tarangambadi) is the regional headquarters. Karaikal district occupies an area of 160 square kilometres. Karaikal is situated on the east coast of India, near latitude 11 N in the deltaic region of the cauveri, experiences tropical maritime type of climate with small daily rang of temperature and moderate rainfall. Karaikal has an annual average rainfall of about 126 cm. There had been an organised Filaria Control activity since 1967 and endemic for Lymphatic filariasis.

The total area of Mahe district is surrounded by North Malabar of Kerala state. It is the sixth least populous district in the country. Mahe district occupies an area of 8.69 square kilometers (3.36 sq mi). According to the 2011 census mahe district has a population of 41,934. Yanam district occupies an area of 20 square kilometres (7.7 sq mi), apart from the town of Yanam itself, the following villages fall under the district jurisdiction. – Kothapeta, Agraharam, Darialatipppa, Farampeta, Guerempeta, Kanakalapeta, Kurasampeta, Mettakur. According to the 2011 census Yanam district has a population of 55,616, roughly equal to the island of Greenland. The district has a population density of 3,272 inhabitants per square kilometre (8,470 / sq mi).

**Study design**

The study was subsequent two phases of treatment rounds consisted of (Das *et al*., 2001) a seven rounds of mass treatment. All four districts had first four rounds of DEC and next three rounds of DEC & ALB, DEC was administered to the study population at the dose of 6 mg/kg body weight and ALBENDAZOLE at 400 µg/kg. DEC, ALB were packaged, after the second round of treatment, the study was continued. we continued to monitor the districts for changes in microfilaria (Mf) prevalence also excluded children of age less than 2 years, pregnant women and critically ill people.

**Mass treatment**

Preciding first round of treatment, the households of villages were enumerated. The enumerating teams visited all households and recorded age, sex and health of inmates. During each round of treatment, the drug distribution teams visited the households and all eligible members (i.e 2-5 years - 1 tab of DEC &1 Tab of ALB, 6-14 Years -2 tabs of DEC&1 tab of ALB ,15 years and above-3 tabs DEC&1tab of ALB) were given the drugs according to their age. People were persuaded to consume the drug after food in the presence of drug distributing voluntier. Those reported with positive side reactions, drug induced adverse effects were given supportive treatment by a medical teams or referred to the nearest PHC. Seven rounds of mass treatment were administered to the study communities. The initial two rounds were given at a 12-month interval and the subsequent five rounds at 12–15-month intervals. The first round of treatment was initiated in June 2004 and the seventh in Feb 2012.

**Microfilaria surveys**

The effect of various rounds of mass drug administration on infection in the population was evaluated by comparing the prevalence of microfilaraemia between pre- and post-treatment periods with DEC and Albendazole . Mf surveys were conducted in all sentinel and spot check sites/wards about 1 week prior to each mass treatment and at the end of 1 year after the seven treatment. In each site and for each Mf survey, we randomly selected 7% of the households and all members were blood sampled.About 500 thick smears were collected in aii sentinel and spot check sites. About 20 $mm^3$ of blood was collected, between 20.00 and 24.00 hours, from each person by finger pricking and prepared into smears of 20 $mm^3$ each on clean glass slides (Sasa 1976). Next day morning, the blood smears were processed – they were dehaemoglobinized in tap water, fixed in methanol and stained in JSB I solution and examined for Mf using a compound microscope. The microfilaraemia status and the number of Mf positive individuals were recorded. As per the institutional ethical guidelines, all the detected Mf carriers in all study arms were treated with a single dose of DEC.

## RESULTS

**Treatment coverage**

The treatment coverage rate of the eligible population ranged from 49% to 84% in different villages (n=4) during different rounds (n=7) of treatment (Table 1). The overall rate for the DEC round ranged from 60.25 to 75.68 and for the DEC & ALBENDAZOLE round from 72.10 to 80.16 (Table 1). A total of 3884002 people in the DEC round and 3187391 in the DEC&ALB round were eligible for treatment during the first round. The changes in Mf rate with each round of mass treatment in various sentinel villages are presented in Figure 1. By the end of 1 year after the sixth mass treatment, the overall Mf rate had declined from pre-treatment level by 86% ,while the relative decline in Mf prevalence, from pre-treatment to post-seventh treatment period, DEC or the DEC&ALB was significant.

The decline in Mf rate was gradual with each mass treatment in DEC rounds, it was observed high even after the first treatment in combined rounds and thereafter remained almost at the same level (Figures 1).

Three of sentinel round and four of spot check sites in the final DEC rounds and three of sentinel and four of random sites in the combined rounds showed zero Mf rate. Figure 1. The reduction in Mf rate was better in the communities treated with DEC &ALB (reduction range: 76–100%) than those treated with DEC (reduction range: 56–100% (Table 2).

**Table 1. Population and Treatment Coverage of the Eligible Population in the Study Area**

| District/Region | MDA Round | Total Population | Eligible Population | Coverage % | Compliance% |
|---|---|---|---|---|---|
| PUDUCHERRY DEC rounds | I (2004) | 729149 | 692642 | 95.26 | 61.79 |
| | II (2005) | 748972 | 705172 | 97.68 | 65.73 |
| | III (2007) | 786174 | 743219 | 97.27 | 88.60 |
| | IV (2008) | 809085 | 764219 | 97.30 | 86.40 |
| DEC and Alb rounds | V (2009) | 819994 | 770300 | 95.95 | 82.17 |
| | VI (2010) | 842120 | 796161 | 96.81 | 77.50 |
| | VII (2012) | 869191 | 819422 | 97.52 | 80.80 |
| KARAIKAL | I (2004) | 175632 | 168623 | 93.09 | 57.11 |
| DEC rounds | II (2005) | 181283 | 173959 | 92.74 | 61.34 |
| | III (2007) | 185120 | 176967 | 92.39 | 65.20 |
| | IV (2008) | 188210 | 179680 | 95.66 | 85.70 |
| DEC and Alb rounds | V (2009) | 190417 | 182184 | 97.16 | 76.10 |
| | VI (2010) | 192486 | 183765 | 97.23 | 64.00 |
| | VII (2012) | 199051 | 186777 | 97.33 | 71.80 |
| MAHE DEC rounds | I (2004) | 37805 | 36018 | 91.23 | 63.55 |
| | II (2005) | 38928 | 37652 | 93.86 | 56.08 |
| | III (2007) | 40439 | 38669 | 93.93 | 49.60 |
| | IV (2008) | 40847 | 38945 | 95.32 | 71.80 |
| DEC and Alb rounds | V (2009) | 42377 | 40267 | 95.77 | NA |
| | VI (2010) | 42242 | 39910 | 94.74 | 70.70 |
| | VII (2012) | 42751 | 40287 | 96.38 | 62.50 |
| YANAM DEC rounds | I (2004) | 30628 | 29644 | 96.87 | 70.76 |
| | II (2005) | 31764 | 30218 | 98.19 | 56.08 |
| | III (2007) | 34864 | 32384 | 98.30 | NA |
| | IV (2008) | 39282 | 35991 | 99.28 | 70.70 |
| DEC and Alb rounds | V (2009) | 39292 | 34188 | 97.92 | 83.33 |
| | VI (2010) | 46977 | 46921 | 99.45 | 70.70 |
| | VII (2012) | 53642 | 47209 | 97.34 | 62.50 |

**Puducherry**

| | Sentinel | | | Spot-check | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| Year | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) |
| 2004 | 2096 | 12 | 0.57 | 1865 | 14 | 0.75 | 3961 | 26 | 0.65 |
| 2005 | 2456 | 3 | 0.12 | 3183 | 25 | 0.78 | 5639 | 28 | 0.49 |
| 2006 | 3210 | 3 | 0.09 | 3220 | 10 | 0.31 | 6430 | 13 | 0.20 |
| 2008 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2009 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2010 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2012 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |

2007 & 2011 MDA not conducted

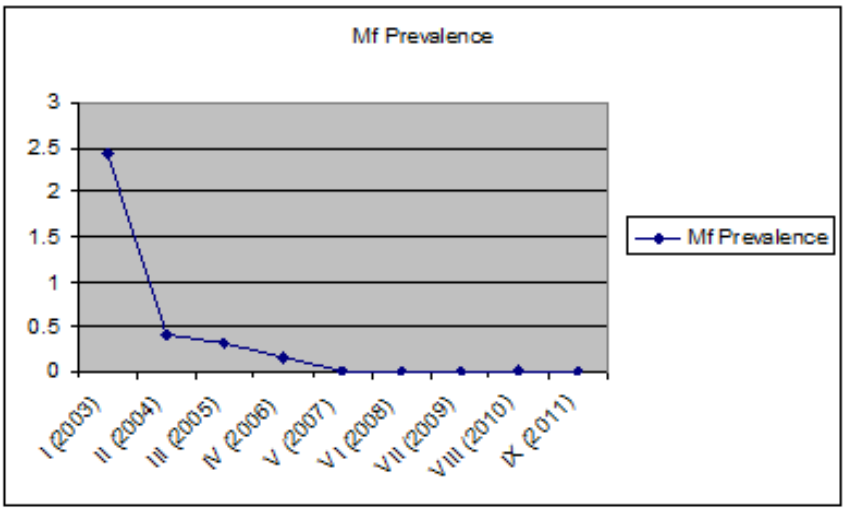


**Fig. 1. Showing the declining trend of Mf Prevalence in different rounds of MDA**

**Table 7. Mf prevalence in sentinel and spot-check villages Karaikal**

| Year | Sentinel | | | Spot-check | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) |
| 2004 | 1500 | 3 | 0.20 | 1500 | 0 | 0 | 3000 | 3 | 0.10 |
| 2005 | 1500 | 0 | 0 | 2000 | 1 | 0.20 | 3500 | 1 | 0.02 |
| 2006 | 1500 | 0 | 0 | 2000 | 2 | 0.10 | 3500 | 2 | 0.05 |
| 2008 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2009 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2010 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |
| 2012 | 1500 | 0 | 0 | 2000 | 0 | 0 | 3500 | 0 | 0 |

2007 & 2011 MDA not conducted

**Table 8. Mf prevalence in sentinel and spot-check villages Mahe**

| Year | Sentinel | | | Spot-check | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) |
| 2004 | 552 | 1 | 0.18 | 500 | 1 | 0.2 | 1052 | 2 | 0.2 |
| 2005 | 520 | 0 | 0 | 600 | 1 | 0.16 | 1120 | 1 | 0.09 |
| 2006 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2008 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2009 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2010 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2012 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |

2007 & 2011 MDA not conducted

**Table 9. Mf prevalence in sentinel and spot-check villages Yanam**

| Year | Sentinel | | | Spot-check | | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) | BSE | No. Mf +ve | Mf rate (%) |
| 2004 | 2052 | 3 | 0.14 | 2000 | 4 | 0.2 | 4052 | 7 | 0.17 |
| 2005 | 630 | 1 | 0.15 | 600 | 2 | 0.3 | 1230 | 3 | 0.2 |
| 2006 | 500 | 0 | 0 | 500 | 1 | 0.2 | 1000 | 1 | 0.1 |
| 2008 | 500 | 0 | 0 | 500 | 1 | 0.2 | 1000 | 1 | 0.1 |
| 2009 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2010 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |
| 2012 | 500 | 0 | 0 | 500 | 0 | 0 | 1000 | 0 | 0 |

2007 & 2011 MDA not conducted

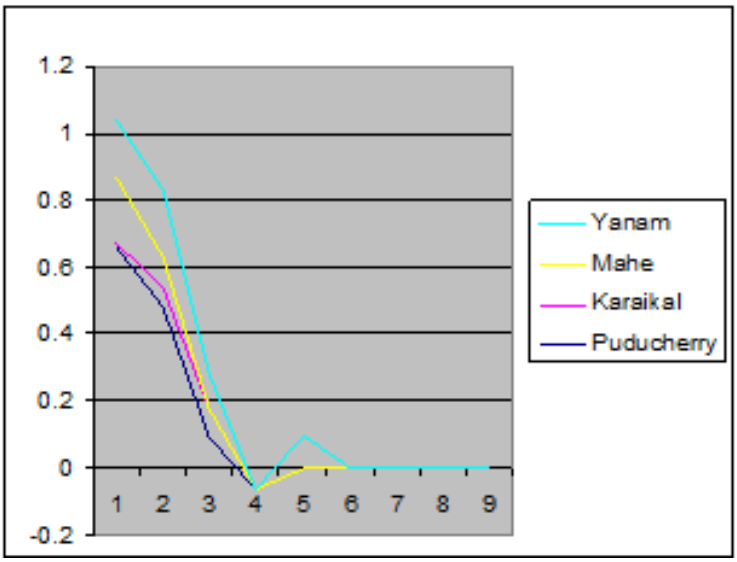


**Fig. 2. Impact of treatment on microfilaraemia**

Seven rounds of treatment resulted in appreciable reduction in the number of Mf carriers with a higher count of Mf. For example Microfilaraemia continued to persist in a proportion of treated population, particularly in those who underwent fewer (1–4) rounds of treatment. Note that microfilaraemia persisted in 1.4 and 2.4% of the people who received even five to seven rounds of treatment with DEC or DEC&ALB, respectively.

## DISCUSSION

Due to the demonstration in clinical trials of the excellent microfilaricidal effect of DEC or DEC&ALB in single dose,

the focus has shifted to their effect at community level. DEC in combination with ALB, are the mainstay of LF elimination programmes in India and Africa, respectively, which together account for 72% of the world's infected population (Michael *et al*., 1996). Therefore, the community level impact of these drugs is being studied widely. In Papua New Guinea, one cycle of mass treatment with a single dose of DEC (6 mg/kg) reduced the Mf rate and intensity by 31% and 70%, respectively (Bockarie *et al*., 1998), two cycles by 34% and 59% in Tanzania (Meyrowitsch *et al*., 1996) and four cycles by 65% and 74% (Balakrishnan *et al*., 1992) and 48% and 60% in India (Das *et al*., 2001). Two cycles of ivermectin (400 µg/kg) in Ghana reduced the Mf rate and intensity by 25% and 40%, respectively (Gyapong 2000) and four cycles by 65% and 80% in an Indian study (Das *et al*., 2001). These studies suggest that one or two treatments exert only limited effect and more than five spaced treatments are necessary to reduce the Mf prevalence to zero. We report the impact of seven rounds of mass drug administration, considered to be adequate to eliminate LF, and hence having significant implications for LF elimination programme.

In this study seven cycles of mass treatment with DEC &ALB reduced the Mf prevalence by 86% and these reductions appear highly significant Ramaiah *et al*. 2000b. However, clinical trials showed that coadministration of DEC with ALB achieves better clearance of microfilaraemia than DEC alone (Ottesen *et al*., 1999). Therefore, problems such as residual microfilaraemia and prevalence of low levels of infection even after seven rounds of treatment, may be overcome by co administration of DEC with ALB. This may help to achieve total interruption of transmission of infection and accelerate the process of elimination.

This study suggests that repeated single-dose mass drug administration with DEC &ALB is an excellent tool to eliminate LF because it is able to achieve, even with modest treatment coverage, 76–86% reduction in prevalence, it is a feasible, cheap and logistically easier strategy (Ramaiah *et al*., 2000b, 2001) and hence, perhaps, very much suitable to large developing countries like India, where other options such as vector control and selective treatment have several ethical and logistic limitations.

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