DOI: 10.7860/JCDR/2023/60979.18019

Original Article

Public Health Section

Evaluation of Triple Drug Administration for Lymphatic Filariasis in Prayagraj District, Uttar Pradesh, India: A Cross-sectional Study

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ABSTRACT

Introduction: Unplanned urbanisation and improper sanitary system in many cities in a developing country increase the cases of vector borne diseases. Among these, filariasis is a major health problem in India. Campaign for triple drug therapy to eliminate the lymphatic filariasis was launched by Government of India but, data assessing the Mass Drug Administration (MDA) coverage and compliance is scarce.

Aim: To assess coverage and compliance of triple drug administration for Lymphatic Filariasis (LF) in Prayagraj district.

Materials and Methods: This community based cross-sectional study was conducted in the Department of Community Medicine at Moti Lal Nehru Medical College, Prayagraj, Uttar Pradesh, India. The duration of the study was 8 days, from 30th October 2021 to 6th November 2021. A total of 1739 individuals belonging to rural and urban area of district Prayagraj were included in the study. Systematic selection was used for selection of subunit. Random selection of 30 subunits from the survey area was done and also Probability Proportional to Estimate Size (PPES) was used, sampling to give everyone in the survey population an equal probability of being selected. A segment of households were randomly selected (typically-10 household) from each subunit (30 subunits, e.g., village). The number and percentage of characteristics were calculated. The data has been entered in MS Excel and analysis was done using Statistical Package for Social Sciences (SPSS) version 23.0.

Results: The mean age of the study participants were 30.78±18.18 years for males and 30.04±17.48 years for females. A total of 1739 persons were covered in post MDA coverage evaluation survey out of which, 1361 persons belonged to rural area and 378 persons belonged to urban area. Ivermectin, albendazole and Diethylcarbamazine (DEC) were swallowed more in urban area (53.27% for each drug) as compared to rural area (18.25% for each drug). Overall, estimated 45.66% drugs were swallowed in district Prayagraj. Adverse drug effect was not found.

Conclusion: The overall coverage of mass drug administration was low (45.66%) and far behind the national target of >85% and it was even worse in urban area where only one-third of the population were offered mass drug administration.

Keywords: Chemoprophylaxis, Drug compliance, Mass drug administration

INTRODUCTION

Developing countries have unplanned development of urban areas and similar for sanitary system which caused increase cases of vector borne diseases [1-3]. In India, filariasis is a major public health problem [4]. A book, Susruta samhita, which had written by Indian physician Susruta in 6th century, mentioned about this disease [5]. LF is a neglected tropical disease, infected person has disfigurement and disability due to damage of lymphatic channel [3]. Lymphatic filariasis caused by filarial nematode W. bancrofti and B. malayi, transmitted by mosquitoes (Culex Quinquefasciatus is a principal vector for LF in India). Lymphatic filariasis is mostly found in 81 tropical and subtropical countries. Approximately, 1.3 billion world population has risk of infection by filarial nematode. A total of 129 million people are infected by LF and 40 million out of 129 million people have seriously disfigured and disabled by filariasis [6]. International Task Force for disease eradication, identified that lymphatic filariasis is potentially eradicable [7]. After than resolution passed on elimination of lymphatic filariasis a public health priority by world health assembly in May 1997 [8,9]. Elimination of lymphatic filariasis program for world depend on MDA, integrated vector management, morbidity management and disability prevention [8,9].

Mass drug administration campaign to achieve elimination the lymphatic filariasis was launched by Government of India. In 2004, in which, annual single recommendation dose of diethylcarbamate was made. This campaign scaling up home based foot care and hydrocele operations. After then, albendazole with DEC was introduced in 2007 and provide in all endemic districts across India [10]. Triple drug therapy (ivermectin, diethylcarbamate and albendazole) has approved by The Ministry of Health and Family Welfare in selective five districts i.e., Varanasi (Uttar Pradesh), Simdega (Jharkhand), Arwal (Bihar), Yadgir (Karnataka) and Nagpur (Maharashtra) [11]. In Prayagraj district, triple drug therapy in MDA round 2019-2020 was began [10]. Transmission Assessment Survey (TAS) is a tool which is used for measurement of circulating filarial antigen in a human population. In 2016, India had achieved coverage of 90% implementing units. A total of 94 out 256 endemic districts has stopped mass drug administration after passing TAS [12]. The incetion of lymphatic filariasis is generally in childhood and accumulate through adulthood, resulting in irreversible chronic disease conditions such as lymphaoedema, elephantiasis and hydrocele [13].

When MDA compliance exceeds 65%-75%, after then transmission interruption will occur for lymphatic filariasis [11]. Irregular implementation of MDA and increased gap between two campaign of MDA or skipped campaign will lead to failure of drug compliance. MDA was inadequate in endemic areas and also large gaps were found between coverage and compliance in many studies [14,15]. So, compliance and coverage of MDA is required for independent assessment by external authorities to find out actual reality. A few studies had been conducted to assess the mass drug administration

coverage and compliance [14,15]. However, only one community based study on MDA coverage and compliance had been found in Prayagraj district by Ram S et al., but previous study was not done with large sample size [16]. So, the present study was conducted with the aim to assess coverage and compliance of triple drug therapy for lymphatic filariasis in Prayagraj district of Uttar Pradesh, India.

MATERIALS AND METHODS

This community based cross-sectional study was conducted in the Department of Community Medicine at Moti Lal Nehru Medical College, Prayagraj, Uttar Pradesh, India. The duration of the study was 8 days, from 30th October 2021 to 6th November 2021. Study was approved by the Institutional Ethics Committee, Registration Number ECR/922/inst/UP/2017). The coverage evaluation survey was done in Prayagraj district according to the national guidelines of National Vector Borne Disease Control Programme (NVBDCP), from November 2021 to December 2021.

Inclusion criteria: All subjects who gave consent for the study were included.

Exclusion criteria: Pregnant women, lactating women, children aged less than 2 years and severely ill person were excluded from the eligible study population.

Sample size calculation: The sample size was calculated by sample size survey builder [17]. The following parameters were used in formula:

Parameter required (n)- default value, expected coverage (p)- 50%, desired precision (δ)- 5% design effect (DEFF)- 4, significance level (α)- 5% (Z=1.96), non response rate (r)- 15%

(The authors did not knew the exact coverage of MDA in Prayagraj district. Therefore, in the present study, the authors chose 50% coverage of mass drug administration. To overcome non respond bias, a large sample size is required, so, the non response rate (r) considered as 15%.

$$n=\frac{(DEFF)\{(Z^2_{\alpha/2}.(p)(1-p)\}}{\delta^2(1-r)}$$

$$n=1807$$

So, in the present study, approximate 1807 participants were required for cluster sampling so, the authors chose 30×10 cluster sampling.

Study Procedure

Systematic method was used for selection of subunit. Random selection of 30 subunits from the survey area was done and also PPES sampling to give everyone in the survey population an equal probability of being selected. A segment of households was randomly selected (typically- 10 household) from each subunit (30 subunits, e.g., village) as it will provide sampling efficacy and also save time during data collection. The Coverage Survey Builder (CSB) had formed two lists (A and B) which helped the selection of household from the segment. The CSB formed a list of random number that corresponds to the household numbers from which all individuals in the survey population was sampled.

Survey data was collected by World Health Organisation (WHO) team from 30th October 2021 to 6th November 2021 and that team was trained by zonal coordinator, WHO. A coin was tossed to choose from list A/B. Each household that corresponded to a number on the selected list (A or B) was included in the survey. All members were enlisted from the survey population in each household, and then, one by one every member on the list was asked questions by interviewer. Questionnaire was developed and validated by team of WHO and this questionnaire was used first time in different areas of Uttar Pradesh. Questionnaire mainly divided into four categories for each drug (albendazol, diethylcarbamate and ivermectin) which were reason for treatment was not offered, reason for treatment was not swallowed, reason for treatment was swallowed and source of information. Questionnaire also included socio-demographic profile of participants like name, gender, age, head of family, urban or rural, block, household member etc., [Table/Fig-1]. The GPS system of

Household Survey to Measure Coverage of IVM + ALB + DEC Among Everyone in the Population for LF

Interviewer Code: I__I__I__I District : I_____I Block : I_____I

Subunit (EA/Village/Other_____) : I_____I HH No: I__I__I__I

Date of Interview (dd/mm/yyyy) : I__I__I/ I__I__I/I__I__I__I__I Household Head : _____

Suvey population:_____

					Ivermectin					Albendazole					DEC						
SR No.	First Name	Sex (M/F)	Age (Years)	HH member Present (Y/N)	Drug Offered? (Y/N/DK)	Reason not offered*1	Drug Swallowed? (Y/N/DK)	Reason NOT Swallowed *2	Reason Swallowed *3	Drug Offered? (Y/N/DK)	Reason not offered*1	Drug Swallowed ? (Y/N/DK)	Reason NOT Swallowed *2	Reason Swallowed *3	Drug Offered? (Y/N/DK)	Reason not offered*1	Drug Swallowed ? (Y/N/DK)	Reason NOT Swallowed *2	Reason Swallowed *3	Source of Informatio n* 4	Adverse drug reaction/s (Y/N)
1																					
2																					
3																					
4																					
5																					
6																					
7																					
8																					
9																					
10																					
11																					

*1 Reason treatment was not offered	
1 = Underage	6= Didn't hear about MDA
2= Pregnant	7= Drug Ran out
3= Breast feeding	8= Nobody came
4= Sick	9= Other
5= Absent	

2* Reason treatment was not swallowed
1= Fear of side effects
2 = Bad taste
3 = Not Sick
4 = Not enough information given
5 = Other

3* Reason treatment was swallowed
1= Fear of Disease(s)
2 = To treat Disease(s)
3 = Because it was given free
4 = Useful information from Drug administrator
5 = Other

4* Source of Information
1= Drug Administrator during IDA
2 = Health workers (MO/ASHA/MPW etc.)
3 = Family/Friends/Neighbour
4 = Pamphlets/Brochures
5 = TV/Social Media
6 = Local Influencer
7 = Other

Y = Yes, N= No, DK = Don't Know

[Table/Fig-1]: Questionnaire prepared for the study participants.

mobile to find accurate location of data collector and also allocation of the subunits was the strategey used to ensure data quality. Field supervisors were allotted for each data collector to observe the interview in a subset of households and also to check the responses recorded by the data collector.

STATISTICAL ANALYSIS

Data was analysed using MS excel and SPSS version 23.0. The number and percentage of characteristics were calculated. Pivot table was used for data analysis.

RESULTS

A total of 1739 individuals were covered in post MDA coverage evaluation survey out of which 1361 individuals belonged to rural area and 378 individuals belonged to urban area. In present study, there were 753 (55.32%) were males with mean age of 30.78±18.18 years and 608 (44.68%) were females with mean age of 30.04±17.48 years. In rural areas, maximum number of participants belonged to 25-29 years age group whereas, in urban area, maximum number of participants belonged to 20-24 years age group. Ivermectin, albendazole and DEC were swallowed more in urban area 725 (53.27%) participants swallowed each drug as compared to rural area where, 69 (18.25%) consumed the drug. Overall, estimated 794 (45.66%) participants swallowed the drug in district Prayagraj. Adverse drug effect was not found in any of the cases. In urban area, ivermectin, albendazole and DEC were swallowed more by 32 (18.93%) females for each drug as compared to males which were 37 participants (17.70%) for each drug. Similarly, in rural area, ivermectin, albendazole and DEC were swallowed more by 339 females (57.76% for each drug) as compared to males which were 386 (51.26% for each drug) [Table/Fig-2].

The most common reason for ivermectin, albendazole and DEC not offered as reported by study population was nobody came followed by underage accounting for 338 (79.72%) and 37 (8.73%) participants, respectively [Table/Fig-3]. The most common reason for ivermectin, albendazole and DEC not swallowed as reported by study population was fear of side-effects followed by the not sick and others [Table/Fig-4]. The most common reason for ivermectin albendazole and DEC swallowed as reported by study population was fear of disease followed by useful information from MDA overall, as well as in rural area whereas, in urban area for ivermectin, albendazole and DEC swallowed, to treat disease was the most common reason [Table/Fig-5].

S. No.	Particulars	Rural (1361)				Rural (total)		Urban (378)				Urban (total)		Grand total	
		Females		Males				Females		Males					
		n	%	n	%	n	%	n	%	n	%	n	%	N	%
1	Persons checked	608	100	753	100	1361	100	169	100	209	100	378	100	1739	100
2	Ivermectin offered	433	71.22	504	66.93	937	68.85	48	28.40	61	29.19	109	28.84	1046	60.43
3	Ivermectin swallowed	339	57.76	386	51.26	725	53.27	32	18.93	37	17.70	69	18.25	794	45.66
4	Albendazole offered	433	71.22	504	66.93	937	68.85	48	28.40	61	29.19	109	28.84	1046	60.43
5	Albendazole swallowed	339	57.76	386	51.26	725	53.27	32	18.93	37	17.70	69	18.25	794	45.66
6	DEC offered	433	71.22	504	66.93	937	68.85	48	28.40	61	29.19	109	28.84	1046	60.43
7	DEC swallowed	339	57.76	386	51.26	725	53.27	32	18.93	37	17.70	69	18.25	794	45.66
8	All drugs offered	433	71.22	504	66.93	937	68.85	48	28.40	61	29.19	109	28.84	1046	60.43
9	All drugs swallowed	339	57.76	386	51.26	725	53.27	32	18.93	37	17.70	69	18.25	794	45.66

[Table/Fig-2]: Triple drugs offered and swallowed by area type and gender.
Number=n; Percentage=%, Total: N

Reasons	Rural		Urban		Grand total	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)	Total (N)	Percentage (%)
Reasons-ivermectin not offered (n)	424	100	269	100	693	100
Underage	37	8.73	0	0	37	5.34
Pregnant women	17	4.01	0	0	17	2.45
Sick	9	2.12	0	0	10	1.44
Absent	11	2.59	10	3.72	22	3.18
Nobody came	338	79.72	259	96.28	596	86.00
Other	12	2.83	0	0	11	1.59
Reasons-albendazole not offered (n)	424	100	269	100	693	100
Underage	37	8.73	0	0	37	5.34
Pregnant women	17	4.01	0	0	17	2.45
Sick	9	2.12	0	0	10	1.44
Absent	11	2.59	10	3.72	22	3.18
Nobody came	338	79.72	259	96.28	596	86.00
Other	12	2.83	0	0	11	1.59
Reasons-DEC not offered (n)	424	100	269	100	693	100
Underage	37	8.73	0	0	37	5.34
Pregnant	17	4.01	0	0	17	2.45
Sick	9	2.12	0	0	10	1.44
Absent	11	2.59	10	3.72	22	3.18
Nobody came	338	79.72	259	96.28	596	86.00
Other	12	2.83	0	0	11	1.59

[Table/Fig-3]: Reasons for triple drugs not offered.

Reasons	Rural		Urban		Total	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)	Number (n)	Percentage (%)
Reasons-ivermectin not swallowed (n)	212	100	40	100	252	100
Fear of side-effects	103	48.58	11	27.50	114	45.24
Not sick	94	44.34	22	55.00	116	46.03
Other	15	7.08	7	17.50	22	8.73
Reasons-albendazole not swallowed (n)	212	100	40	100	252	100
Fear of side-effects	103	48.58	11	27.50	114	45.24
Not sick	94	44.34	22	55.00	116	46.03
Other	15	7.08	7	17.50	22	8.73
Reasons-DEC not swallowed (n)	212	100	40	100	252	100
Fear of side-effects	103	48.58	11	27.50	114	45.24
Not sick	94	44.34	22	55.00	116	46.03
Other	15	7.08	7	17.50	22	8.73

[Table/Fig-4]: Reasons for triple drugs not swallowed.

Characteristics	Rural		Urban		Total	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)	Number (n)	Percentage (%)
Reasons-ivermectin swallowed (n)	725	100	69	100	794	100
Fear of disease	496	68.41	29	42.03	524	65.99
Useful information from MDA	229	31.59	40	59.97	270	34.01
Reasons-albendazole swallowed (n)	725	100	69	100	794	100
Fear of disease	496	68.41	29	42.03	524	65.99
Useful information from MDA	229	31.59	40	59.97	270	34.01
Reasons-DEC swallowed (n)	725	100	69	100	794	100
Fear of disease	496	68.41	29	42.03	524	65.99
Useful information from MDA	229	31.59	40	59.97	270	34.01

[Table/Fig-5]: Reasons for triple drugs swallowed.

DISCUSSION

This present study was conducted in Prayagraj district, where distribution of males and females were found to be 55.32% and 44.68%, respectively. Similar distribution of males and females were found in studies done by Singh SK et al., which were 52.8% and 47.2%, respectively [18]. Annual mass drug administration is helpful to break transmission of LF therefore, 5 to 6 rounds of annual MDA are required. A 65% treatment coverage should be accomplished in every round of MDA [19]. According to WHO, two annual rounds of a triple drug ivermectin, DEC and albendazole are required for achieving sustained clearance of lymphatic filariae [20]. In present study, the coverage, effective coverage and compliance of MDA were 60.43%, 45.66 and 75.91% respectively overall; 68.85%, 53.27%, 77.37% respectively in rural area and 28.84%, 18.25%, 63.30% respectively in urban area. But, Nayak BC et al., found high coverage, effective coverage and compliance of MDA in 94%, 88%, 93%, respectively overall; 95%, 88%, 93% respectively in rural area and 92%, 86%, 94%, respectively in urban area [21]. Similarly, study done by Kulkarni P et al., reported coverage, effective coverage and compliance of MDA in 93.9%, 83.2%, 88.5%, respectively. Overall, 95.1%, 87.9%, 92.4% in rural area and 89.9%, 68.2%, 75.8%, respectively in urban area [22]. Panika RK and Sahu R, found in his study that coverage, effective coverage and compliance of MDA was 86.6%, 64.3%, 74.3%, respectively [23]. Barman SK et al., found overall coverage, effective coverage and compliance of MDA (albendazole and DEC) were 51.7%. 19.1%, 36.9%, respectively in study area [24].

Similar findings in the study done by Haldar D et al., reported overall coverage, effective coverage and compliance of MDA was 65.5%, 50%, 75.2%, respectively [25]. Similarly, the study done by Banerjee S et al., reported overall coverage, effective coverage and compliance of MDA was 55.2%, 48.5%, 87.9%, respectively [26].

The study done by Banerjee S et al., reported coverage, effective coverage and compliance of MDA was 76.4%, 64.1%, 83.9% respectively for DEC and 74.8%, 63.3%, 84.6% for albendazole and DEC [27]. Panika RK and Sahu R found in his study that coverage, effective coverage and compliance of MDA was higher in males than females which was not similar to present study [23]. But in Bhatia V et al., reported coverage, effective coverage and compliance of MDA was higher in females than males which was similar to present study [28]. According to Bhue PK et al, the most common reason for not offering drug was beneficiaries being absent at their home during drug distribution [29].

In present study, ivermectin, albendazole and DEC was not swallowed as reported by study population was sick followed by fear of side-effects. But, in Panika RK and Sahu R showed in his study that, the main reason for non consumption was not suffering from concerned disease followed by fear of side-effects, Forget to take tablets, not present at home during distribution of drug etc., [23]. According to Haldar D et al., most common reason for non consumption was fear of side-effects followed by forgotten to consume, not at home during the MDA implementation and didn't have the disease [25]. In a study by Banerjee S et al., found that, most common reason for non consumption was fear of side-effects followed by forgot to consume [26]. Haldar D et al., showed that, 25 (7.72%) individual reported adverse event. Where, 72.0%, 24.0%, and 8.0% were complained of dizziness, drowsiness and vomiting, respectively [25]. According to Kumar S et al., found 3 cases (0.59%) had adverse reactions, all are mild cases like giddiness, vomiting and gastric irritation [30]. But, no adverse reaction found in the present study.

Limitation(s)

One of the major limitation in the present study was small sample size and recall bias.

CONCLUSION(S)

The overall coverage of MDA was low (45.66%) and almost half of the study population were offered MDA overall and it was even worse in urban area where, approximately one-third of them were offered MDA. The offer- swallow gap was markedly higher in rural area. The main reasons for not offering MDA as reported by study population was that, nobody came to offer MDA and people were not present in house. The main reason for not swallowing MDA as reported by study population was perception that 'if they are not sick followed by fear of side-effects and others'. Drug distributor training is very important. Training of drug distributor should be demonstrative and comprehensive which will increase patients because, they will direct contact to public. Drug distributors have to ensure the consumption of drugs in their presence and visit every household in allotted area. Information education and communication activities are required to create awareness regarding the need and safety before MDA round. Develop of better drug delivery strategies and system. Strengthening monitoring system as many reported that nobody came to offer MDA. Special pre-MDA Information, Education and Communication (IEC) activities in rural areas to bridge offer- swallow gap.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Oct 21, 2022
- Manual Googling: Jan 19, 2023
- iThenticate Software: Feb 17, 2023 (17%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:

- Financial or Other Competing Interests: Funded by National Health Mission, Uttar Pradesh
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Oct 20, 2022**
Date of Peer Review: **Dec 10, 2022**
Date of Acceptance: **Feb 23, 2023**
Date of Publishing: **Jun 01, 2023**