



**PHARMACOVIGILANCE JOINS HANDS WITH NATIONAL DEWORMING PROGRAMME IN ANDAMAN & NICOBAR ISLANDS.**

**Dr. Priyanka Hotha<sup>1</sup>, Dr. C. Dinesh M. Naidu<sup>\*2</sup>, Nimisha Elezebeth Zachariah<sup>3</sup>**

<sup>1</sup>Assistant Professor, Department of Pharmacology, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair, India.

<sup>2</sup>Professor & Head, Department of Pharmacology, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair, India.

<sup>3</sup>Pharmacovigilance associate, Department of Pharmacology, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair, India.

**\*Corresponding Author: Dr. C. Dinesh M. Naidu**

Professor & Head, Department of Pharmacology, Andaman & Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair, India.

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**ABSTRACT**

**Background:** In India, preschool and school going children are expected to have a risk of soil transmitted helminthes worm infection. On national deworming day (NDD), tablet Albendazole was given to school going children to protect them from worm infection through a single fixed day approach. **Objective:** The aim of this study is to safeguard the health of children and adolescents against worm infection by monitoring as well as reporting ADRs against tablet Albendazole 400mg and thereby promoting drug safety and compliance. **Methods:** An email was received at the ADR monitoring centre, Port Blair from the National Health Programme division of National Coordinating Centre, PvPI, IPC, directing the AMC personnel to monitor the adverse events occurring due to the administration of tablet Albendazole 400mg on NDD. They also instructed to sensitize all the health care workers and school staffs involved in the National deworming Programme regarding the role and importance of pharmacovigilance in promoting drug safety and also train them to monitor, collect and report the ADRs from the schools and notify them to ADR Monitoring Centre. **Result:** This was an observation study. We included a total of 6 schools which were nearby the ADR monitoring centre. Out of them we found a total 10 ADRs which equally affected male and female students. Nausea, vomiting and stomach ache were the most commonly reported ADRs. **Conclusion:** Using focused pharmacovigilance programme, it is feasible to ensure safety against Albendazole in community programmes like the National Deworming Programme. Hence, for a safe deworming programme, PvPI should be collaborated as a routine activity, to ensure safety against Albendazole.

**KEYWORDS:** Adverse Drug Reaction, Pharmacovigilance, Albendazole, National Deworming Programme.

**INTRODUCTION**

An adverse drug reaction (ADR) is defined as, any noxious change which is supposed to be due to medicine, occurs at therapeutic dose, needs treatment or requires a decrease in dose or indicates caution in the imminent use of the drug.<sup>[1]</sup> Pharmacovigilance plays a significant role in reducing drug related harm to the patients. World health organization (WHO) defines pharmacovigilance as the science and activities which is relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related harms.<sup>[2]</sup> On NDD, all children aged 19 years and below were given tablet albendazole 400mg under safe deworming programme. By collecting and reporting the drug related ADRs, PvPI enhances drug safety and improves health quality of Indian population. Worm infestation or soil transmitted helminthes (STH) is a major and serious health issue in India. Around 225 million preschool and school going children are expected to have a risk of

worm infection. India accounts for 65% of soil-transmitted helminth (parasitic worms) cases in South East Asia and 27% of cases globally.<sup>[3]</sup> To safeguard school going children and adolescents from worms infestation through a single fixed day approach, tablet Albendazole 400 mg was given to children aged 19 years and below in different defined places i.e. child care centres, schools and colleges. This was followed by a "mop-up day" to deworm children who were missed out on National Deworming Day (NDD).<sup>[4]</sup> Many Public Health Programmes (PHPs) involve the direct administration of medicines to patients, students and communities, for the prophylaxis, treatment and eradication of diseases. By collaborating with PHPs, PvPI exploits the benefits of the Programme, thus maintaining public reliance towards the PHPs. PvPI and Safe deworming Programme can derive mutual benefits from each other. By monitoring and reporting ADRs on NDD, we can have remarkable positive impact on the

implementation and success of the National Deworming Day. The aims of this study is to safeguard the health of children and adolescents against worm infestation by monitoring as well as reporting ADRs against tablet Albendazole. By monitoring, collecting and reporting ADRs, we can build a public confidence that the drug administered during national deworming day is harmless and tablet Albendazole is a highly safe drug.

#### MATERIAL AND METHOD

Pharmacovigilance is always concerned about drugs safety. In this regard, an email was received by the patient safety pharmacovigilance associate (PSPvA), Andaman and Nicobar Islands Institute of Medical Sciences (ANIIMS), Port Blair. The email was sent by the National Health Programme (NHP) division of National Coordinating Centre (NCC)- PvPI, Indian Pharmacopoeia Commission (IPC). They directed the PSPvA to monitor the adverse events (AE)s due to administration of tablet Albendazole 400mg on NDD which was scheduled on 10<sup>th</sup> February 2020, under the safe deworming programme. They informed to sensitize the health care workers, deployed for Albendazole administration in the nearby schools, child care centers, aanganwadis and colleges. In case any AE occurred, the health care workers were requested to report them by contacting the ADR Monitoring Centre (AMC), Port Blair or through other modes of AE reporting such as through the PvPI helpline no.(toll free no.-1800 180 3024), mobile application- ADR PvPI or by sending an email to the IPC. The email was attached with annexure-1 (NDD School visit record), annexure -2 (NDD ADR recording form), NDD state nodal officer's contacts, NDD date sheet and NDD poster for 2020, for a successful and safe national deworming day.

Events were started to complete our goal towards safe deworming programme 2020.

##### a. Formation of an expert team

The committee comprised of 5 members which included the AMC coordinator, PSPvA, NDD programme coordinator from Directorate of health Services (DHS) and Joint secretary from DHS (State nodal officer). The committee selected six nearby schools for implementing the safe deworming programme. The objective of the committee was to supervise activities concerning NDD and conduct an orientation cum training programme on pharmacovigilance for nodal teachers, Accredited Social Health Activists (ASHA) and ANMs. The training programme highlighted the purpose, roles and importance of PvPI.

##### b. Training on focused pharmacovigilance

The expert committee sensitized the nodal teachers, Urban ASHA workers and ANMs. They briefed them regarding the collaboration and importance of PvPI in NDD, role of focused pharmacovigilance against tablet Albendazole administration, expected ADRs related to tablet Albendazole, how to manage AEs if any ADR

occur and methods and significance of ADR reporting. i.e. most common ADR with albendazole are nausea, vomiting, stomach ache, headache etc. if any mild ADR will be reported, give them symptomatic treatment and report it. If any serious ADR will be reported, immediately hospitalized and report it.

##### c. Further sensitization

To provide more awareness regarding the collaboration of PvPI with NDD, PSPvA along with other AMC personnel visited the selected schools and sensitized the school principal and healthcare workers about the role and implication of PvPI with NDD. PSPvA furnished them with annexure-1, annexure-2 and NDD poster for awareness and also instructed them how to fill the annexures and report ADRs if any ADRs occurred.

##### d. Data analysis

The data was collected after the mop up day of safe deworming programme 2020. One copy of NDD result and mop up day results with filled Annexure 2 form was delivered to the AMC, department of pharmacology, ANIIMS, Port Blair and a second copy was delivered to DHS.

All school going students' data including demographics, treatment and adverse events were entered using individual student's IDs and initials.

#### RESULT

This was the first time when pharmacovigilance joined hands with the National Deworming Programme, in the serene group of Andaman & Nicobar Islands. On NDD, all children aged 19 years and below were given tablet albendazole 400mg under safe deworming programme. Because of the availability and feasibility, we were only able to cover 6 schools which were close to the AMC, Port Blair. Approximately 10,000 children were administered tablet Albendazole 400mg on 10<sup>th</sup> February i.e. NDD and on 17<sup>th</sup> February i.e. mop-up day, under the safe deworming programme. We received the ADR forms from the 6 schools and ANIIMS at AMC within a definite day. Among the 10,000 students administered tablet Albendazole 400 mg, only 10 students complained of an ADR. The number of girls and boys suspected to have experienced an ADR was found to be equal. Out of the 10 students, 6 students had vomiting, 2 students had nausea and 2 students had stomach pain. All the ADRs related to tablet Albendazole i.e. nausea, vomiting and abdominal pain, recovered within the next day. None of the students complained of any serious ADR i. e. death, life-threatening, hospitalization, significant disability/incapacity or congenital abnormality.<sup>[5]</sup> After receiving the drug reaction monitoring form, the details were filled in the suspected ADR reporting form and the cases entered in vigiflow, a data entry software. The reports were sent to the DHS and also emailed to NCC-PvPI, IPC.

## DISCUSSION

In India, soil transmitted helminthes (20%) or parasite worm infestations are very serious in health and mental development and its negative impact is implemented with the Ministries of Women and Child Development and Human Resource Development.<sup>[4]</sup> For deworming, single-dose Albendazole (400 mg) is recommended as a public health intervention for school going children between 5– 14 years of age.<sup>[6]</sup> In order to address this problem, India has initiated the NDD.<sup>[7]</sup> India's first and second NDD was held in February 2015 and 2016 respectively. Around 140 million children were treated in 12 states and 270 million children were treated in 36 states and union territories countrywide respectively.<sup>[8]</sup> NDD falls under the purview of the Extended Gram Swaraj Abhiyan, and is also dedicated to educating about the nutritional uptake in all school going children and adolescents and has huge contribution to the cause of Anemia Mukht Bharat and Poshan Abhiyaan, under the National Nutrition Strategy, formulated by Niti Aayog in December 2017, with revelation towards anemia and malnutrition reduction by 2022.<sup>[9]</sup> Deworming with tablet Albendazole is effectively improved the nutritional status of pre school and school going children. Since the prevalence of STH is high, repeated mass treatment for at least five sequential years is necessary to prevent reinfection.<sup>[10]</sup> Albendazole is an anthelmintic drug. Most common side effects of Albendazole are stomach pain, nausea, vomiting, headache, temporary hair loss, elevated liver enzymes, fever. etc.<sup>[11,12]</sup> While in our study, the most commonly reported side effects were vomiting, nausea and stomach pain, which were not serious and did not require an extensive medical treatment. Albendazole Sulfoxide, the active metabolite of Albendazole, causes selective degeneration of cytoplasmic microtubules in intestinal and tegmental cells of intestinal helminths and larvae. The metabolite binds to the B-tubulin subunit of the helminth's microtubules and thus inhibits microtubule polymerization. It causes impaired glucose utilization and causes a decrease in parasite's glycogen stores. By this mechanism, Albendazole causes energy depletion, which leads to the immobilization of the parasite and subsequent death and It prevents newly hatched insect larvae (worms) from growing or multiplying in your body.<sup>[13]</sup> Using tablet Albendazole for deworming is an evidence-based, globally-accepted and effective solution which is used to control worm infections in all children. Pharmacovigilance is a clinical and scientific discipline that has an influence on the public health environment. Pharmacovigilance in India was started in 1986 with a formal ADR monitoring system, under the observation of the drug controller general of India (DCGI). India joined the World Health Organization Programme for International Drug Monitoring in 1998. The National Programme of Pharmacovigilance was launched in 2005 and was retitled as the Pharmacovigilance Programme of India in 2010.<sup>[14]</sup> A number of AMC function under the IPC, Ministry of Health and Family Welfare, Government of India, to

monitor drug-related adverse events.<sup>[15]</sup> Indian Pharmacopoeia Commission will help the pharmacovigilance programme to expand all over the country. Around 270 AMCs are functioning in various places in India. The Union health ministry desires to increase AMCs.<sup>[16]</sup> In public health programmes, a large number of patient population consume drugs in a systematic manner and hence there might be chances to develop ADRs. In different projects, some safety issues are being addressed to various disease control programmes i.e. Chagas, HIV/AIDS, Malaria, Tuberculosis, etc.<sup>[17]</sup> Unmonitored ADRs might generate harm to the patients and this concern also reflects on prophylaxis, treatments and elimination related to PHPs. At the same time, this might be effective in generating valid and valuable data that might affect decision making in future. The NDD programme is a cost-effective programme. Deworming has shown to reduce absence in schools, improve health, nutritional and learning outcomes for children and also increase the possibility of higher-wage jobs later in life as per global substantiation. By deworming children, we effectively reduce the general spread of worm infestations in the community. Treating school age children can reduce the total burden of disease due to intestinal worm infections by 70% in the community as a whole.<sup>[18]</sup> By Collaborating Pharmacovigilance programme with National Deworming Programme, it ensure drug safety against Albendazole. To enhance public awareness toward drug safety, pharmacovigilance should be integrated with public health programme as advance approach i.e. National deworming programme. The limitation of our study was that we could include only a few number of schools which was close to the AMC because of the availability and feasibility. This resulted in underreporting of 10 ADR reports. In addition to that, some students might have directly gone to the hospital with complaints of ADRs and were treated in hospitals, which were not reported. Because of lack of relevant data, we are not able to compare our results with other data. For successful collaboration of pharmacovigilance programme with Safe Deworming Programme, all health care professional and school staff should have periodic training on focused pharmacovigilance. This is very important for conducting pharmacovigilance activities.

## CONCLUSION

In National Deworming Programme, Albendazole drugs are used for deworming the school going children. Along with deworming, drug monitoring, reporting and active follow-up surveillance are the most useful methods for conducting pharmacovigilance activities. Using focused pharmacovigilance programme for ensuring safety against Albendazole is feasible in National Deworming Programme. Hence, for safe deworming programme, PvPI should be collaborated as routine activity to ensure safety against Albendazole.

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**Abbreviations**

ADR- Adverse Drug Reaction  
 WHO- World Health Organization  
 Pvpri- Pharmacovigilance Programme Of India  
 STH- Soil Transmitted Helminthes  
 NDD- National Deworming Day  
 PHP- Public Health Programmes  
 Pspva- Patient Safety Pharmacovigilance Associate  
 NHP- National Health Programme  
 NCC-National Coordinating Centre  
 IPC- Indian Pharmacopoeia Commission  
 AE - Adverse Events  
 AMC- ADR Monitoring Centre  
 ASHA - Accredited Social Health Activists  
 DCGI - Drug Controller General Of India