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Adverse Events Management During Albendazole Mass Drug Administration: A Pilot Study Experiences from A District of Andhra Pradesh, India

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ABSTRACT

Focussed Surveillance of Albendazole Mass Drug Administration

This pilot study describes the field experiences of integrated approach of regional Adverse Drug Reactions monitoring centre (AMC) under Pharmacovigilance Programme of India (PvPI) and National de worming program in Nandyal district of Andhra Pradesh, India in adverse events monitoring associated with albendazole mass drug administration in school children. Though 2% of adverse events (AE) reported as non - serious in nature, found few gap areas in management of children those encountered with such adverse events. Therefore, necessary Standard Operating Procedures and risk management plan to be developed and healthcare workers trained accordingly to minimize the risk.

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Key Message

All AMC staff should be present at site during mass drug administration to prevent Fatalities on site. Should manage patient by shifting to hospital and providing treatment. Hospital attached to AMC should treat ADR patients immediately on mandatory basis.

Introduction

The National deworming programme under the ministry of health and family welfare, government of India with the objective to deworm all preschool and school - aged children/adolescents between the ages of 1 to 19 years at preschools, and schools including government, government aided and private schools on a single day approach i.e. 10th February and 10th August every year across all states and union territories. The exercise aimed at a massive target of 270 million children in 536 districts of the country [1]. As per the program strategy, government, private and Anganwadi (pre school) teaches administer the deworming tablet to children. The Pharmacovigilance Programme of India (PvPI) has been implemented to monitor, report, assesses and communicate the adverse drug reactions (ADRs) associated with the use of medicines [2]. As per the WHO guidelines the PvPI has been integrated with public health programs to ensure the safety of medicines used in their respective programs including National de worming program to monitor the safety of albendazole during its mass drug in school children [3]. If any signals detected from the ADRs data, shall be communicated to respective program for better patient care. There were reports available that ADRs associated with the use of albendazole in mass drug administration; that triggered to initiate this pilot study to understand the developments and challenges under the integration at the field level, the Santhiram medical college and general hospital, a regional ADRs monitoring centre under PvPI, in Nandyal district of Andhra Pradesh, India was choose for this study based on their voluntary interest [4,5].

Material and Methods

Study settings and design

A community based prospective study was conducted on primary, secondary and higher secondary school children of age group 5 years to 14 years both male and female in Nandyal district, Andhra Pradesh, a southern part of India after the approval from Institutional Human Ethics Committee. A total of ten government schools were randomly selected, where drug was administered by Anganwadi workers and positive response by the school principals to participate in national deworming programme. The technical support was provided by Pharmacovigilance Programme of India (PvPI) along with Adverse Drug Reactions monitoring Centre

(AMC) at Santiram Medical College. A training programme for nurses, anganwadi workers, other health care workers on National deworming day, mass drug administration, strict confidentiality aspects, suspected adverse drug reaction (ADR) reporting form, modes of ADR reporting, monitoring and management was conducted seven days prior to National De worming day. School Principals and staff members were also sensitized for the same prior to programme conduction. On National De worming day (10th February 2020), Albendazole single dose of 400 mg tablet was administered post lunch with water simultaneously to all 750 children located at ten schools in the Nandyal district different places AMC team members were deployed at each school to ensure albendazole dosing. Subsequently each child was monitored for 6 hours for adverse events, if any. The sample size caluculator used based on total population of students from all schools in Nandyal, with 5% precision, confidence level of 95%.

The details of each student, school and teachers, AMC focal person was collected in form I while the suspected ADR and relevant details were collected in PvPI suspected ADRs reporting form (form II). An approval from AMC's Pharmacovigilance committee and institutional ethics committee approval was obtained to conduct this study. Statistical analysis: data was analyzed using SPSS software version 22, for frequency tables and Chi Square test is applied and cross tabulated for drug reaction versus age, gender and starting time for reaction occurred. P value considered is 0.05, values less than 0.05 was considered as highly significant to prove correlation between the observed values. Severity assessment was done by modified Hartwig Siegel scale, while preventability assessment by Schumock Thorton scale. The root cause analysis was done using James Reason Model (The Swiss Cheese Model of Accident Causation.

Results

The reported adverse effects were moderate (non-serious) in nature. Ninety eight percent of the study participants administered with Albendazone did not develop any adverse effects. Two percentages (16 Children) developed with adverse events; Out of these 1%(8 children) were reported with stomach ache, and the remaining 1% (8 children) were reported with vomiting, headache and Rash. The causality assessment was performed as per WHO scale. All the cases had positive temporal relationship between drug and event, when reaction started in 15 minutes of administration of drug. Dechallenge was positive with stoppage of drug, therefore causality assessment indicated probable type of reaction. The severity of the events as per Modified Hartwig and Siegel Scale found that 1% (8 children) were moderate i.e. level 3. The remaining 1% (8 children) those developed with stomach ache the severity was found to be moderate i.e. level 4b. All children those encountered with adverse events were treated symptomatically and were discharged after recovery. No fatality due to adverse events was seen.

In order to build the confidence of the parents and public it becomes pivotal for ensuring the safety of albendazole used in mass drug administration. Therefore the PvPI and National De worming program aligned at national level for its effective implementation of adverse events monitoring with the use of albendazole. The present pilot study was conducted to understand the issues prevail at regional level. The lesson learnt from the present pilot study that the AMC had played an important role with active participation at the site of mass drug administration identifying ADR'S and immediate shift to hospital for treatment of drug reaction children inspite of challenges faced to provide treatment. This Prevented deaths of ADR affected children. Hurdles were faced by AMC team due to miscommunication. This attitude might be because of hospital reputation, media issues etc.

Discussion

Therefore based on this study an advisory note from PvPI to all AMCs may be issued stating that the AMCs and its attached hospitals shall be responsible for supporting the de worming programme not only by monitoring and reporting of ADRS and also treating the children if affected with ADRs. This study was found that there was lack of regional level coordination among the PvPI-AMC, de worming programme staff and state drug control department in case of ADRs management and preventive action - therefore an appropriate Standard Operating Proceudre and guideline will ensure in effective management and better outcomes. The NCC PvPI to provide adequate training pre and post training programme on ADRs management to the de worming staff and other health workers. An appropriate risk management and minimization plan with respect to albendazole mass drug administration to be developed by PvPI in consultation with AMCs and other stakeholders. Based on this pilot study, the practical challenges of reporting and managing adverse events in the context of albendazole mass drug administration requires policy amendment.

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