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Adverse events associated with Measles and Rubella vaccination campaign 2019 in India

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Purpose: The purpose of this study is to study the various adverse reactions caused post measles and rubella vaccination done during measles rubella (MR) vaccine campaign in India.
Materials and Methods: Prospective, observational study was done in a government tertiary care pediatric intensive care unit. Children aged between 9 months to 15 years, who presented with adverse effects (severe enough to warrant admission) within 7 days of MR vaccine administration.
Results: Most common presenting complaint was fever (44.8%), followed by vomiting (34.5%), abdominal pain and dizziness (31%). Abnormal body movements were noted in two children (6.8%) on first day and in one child on fifth day of vaccine administration. Two children (6.8%) presented with generalized macular rashes all over the body on 4th day after vaccination. Altered sensorium on same day of vaccine administration was the presenting symptom of one child. All children improved gradually and were discharged after few days with no mortality or long-term morbidity. Investigations were done according to the protocol of the unit; nothing came significant to be reported. Neither of the children had positive blood culture.
Conclusion: MR vaccination programs are scientifically sound, highly recommended and proven effective globally. Causality assessment of adverse events is still an evolving science, and despite taking all the measures and adopting all the available scientific methods, sometimes it is not possible to incontrovertibly prove the causal association of an event with a vaccine. Much more advancement in this area is needed.

Keywords: Measles vaccine, Rubella vaccine, Measles rubella campaign, Adverse events

Introduction

Government of India, ministry of health and Family welfare has launched one of the world's largest measles rubella (MR) vaccination campaigns as part of its national strategy to eliminate measles and rubella disease from the country by 2020. The phased MR campaign has been targeted to vaccinate more than 35 million children in the age group of 9 months to 15 years across the country with one dose of MR vaccine. The aim of the campaign was to rapidly build up immunity for both measles and rubella in the community therefore requiring 100% coverage [1]. The MR vaccination campaign was launched in Kerala on 3rd October 2017 as the second phase of the National Immunization Program aiming to eliminate MR by 2020. The drive was carried out in schools, community centers, and medical institutions [2].

The MR vaccination campaign dose has been given to all targeted children, irre-

spective of prior measles-rubella immunization status or disease status. It is in addition to routine immunization dose. MR vaccine used in the campaign is a safe and effective vaccine that has been in use for over 40 years and in more than 100 countries across the world. Vaccine being given in MR campaign is produced in India and is prequalified by the World Health Organization [1].

Although vaccine is proven to be safe, there is a potential risk of an adverse reaction, as with any other drug or medication. The adverse event following immunization (AEFI) is defined as "a medical incident that takes place after immunization, causes concern and is believed to be caused by the immunization" [3]. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding, a symptom, or a disease. Like with any other vaccine, MR vaccine can cause mild pain and redness at injection site along with low grade fever, rash, and muscle aches, which subsides on its own. However, there are case reports of children in whom signs of both developmental regression and gastrointestinal symptoms developed shortly after measles, mumps, and rubella (MMR) vaccination [4]. The measles virus used in the MMR vaccine is a live attenuated virus that normally causes no symptoms or only very mild ones. However, wild-type measles can infect the central nervous system and even cause post-infectious encephalomyelitis, probably as a result of an immune-mediated response to myelin proteins [5-7].

Tolerance to vaccine associated adverse events is generally lower as these are administered to healthy children unlike other pharmaceutical products used in morbid populations. Ours is a pilot study to report the range of adverse effects following the MR vaccine administration during recent campaign in Gwalior region.

Materials and Methods

This prospective observational study was conducted in Kamla Raja Hospital, Gwalior, which is a tertiary care center, in the months of January and February 2019, immediately following the round of MR vaccination. Total 29 children, in the age group of 9 months to 15 years, who presented with adverse effects (severe enough to warrant admission) within 7 days of MR vaccine administration, were included. Demographic and clinical profile of children were noted. Informed verbal consent was obtained from all the subjects before start of data collection and anonymity of data was assured. Clearance from the institutional ethical committee of Gajra Raja Medical College, Gwalior, India was taken (IRB approval no., 872; 12-July-2019).

Table 1. Age and gender distribution of children enrolled in study

Gender	Age group			
	9 mo–5 yr	6 yr–10 yr	11 yr–15 yr	Total
Male	5 (17.2)	4 (13.8)	5 (17.2)	14 (48.2)
Female	2 (6.8)	5 (17.2)	8 (27.6)	15 (51.8)
Total	7 (24.1)	9 (31.0)	13 (44.9)	29 (100.0)

Values are presented as number (%).

Results

Of the total 29 children who were admitted in pediatric ward, 14 (48.2%) were male. Characteristics of study population are summarized in Table 1. Mean age was 9 years with most of the children (44.8%) in the age group of 11 to 15 years (Table 1).

Most common presenting complaint was fever (44.8%), followed by vomiting (34.5%) and abdominal pain and dizziness (31%). Abnormal body movements were noted in two children (6.8%) on first day and in one child on fifth day of vaccine administration. Two children (6.8%) presented with generalized macular rashes all over the body on 4th day after vaccination. Altered sensorium on same day of vaccine administration was the presenting symptom of one child (Table 2).

All children improved gradually and were discharged after few days with no mortality or long-term morbidity. Investigations were done according to the protocol of the unit; nothing came significant to be reported. Neither of the children had positive blood culture.

Table 2. Presenting complaints of the children post vaccination

Presenting complaints	Frequency (%)
Fever	13 (44.8)
Vomiting	10 (34.5)
Abdominal pain	9 (31.0)
Dizziness	9 (31.0)
Restlessness	6 (20.7)
Abnormal body movement	3 (10.3)
Loss of consciousness/syncope	2 (6.8)
Weakness	2 (6.8)
Rashes	2 (6.8)
Cough/cold	2 (6.8)
Headache	1 (3.4)
Altered sensorium	1 (3.4)

Discussion

Vaccine associated adverse events are more likely to be noticed and communicated and can often significantly impact immunization programs.

In our study, there was no gender predilection. This is in contrast to the findings of the study done by Shohat et al. [8] which demonstrated higher rates of adverse effects like fever and rash in females following routine MMR vaccination.

Mean age of our study population was 9 years. We could not find any study of the catch-up immunization or MR vaccination campaign (range of age group, 9 months to 15 years), so no comparison of mean age can be done.

Fever and vomiting were the most common presenting complaints in our study population. Fever and rash were the most common reported adverse events following MMR vaccination in previous studies [8,9]. Ten percent of our study population presented with abnormal body movement/seizure post MR vaccination. Few studies done previously also report association of MMR vaccine with febrile seizures [10-12].

The risk of AEFI is always weighed against the risk of not immunizing a child. It is only when the benefit outweighs the risk, that a vaccine is considered safe. However, even at a relatively low rate, because of the high absolute number of beneficiaries, there is a risk of a few serious adverse events in the vaccinated children [13].

The limitations of the study are that the study covered only a limited population of vaccines who got admitted in our institution resulting in the findings to be context specific and may not be applicable in all situations.

In conclusion, MR vaccination programs are scientifically sound, highly recommended and proven effective globally. Causality assessment of adverse events is still an evolving science and despite taking all the measures, and adopting all the available scientific methods, sometimes it is not possible to incontrovertibly prove the causal association of an event with a vaccine. Much more advancement in this area is needed.

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