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Original Research Article

Incidence of adverse events following immunization (AEFI) among infants after immunization with primary doses of scheduled vaccines in district Srinagar (J&K)

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ABSTRACT

Introduction: Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. However, like other medicinal products, vaccines are not free from adverse reactions. AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The reporting of AEFI's from the routine system is inadequate due to many reasons. Hence this study was conducted to throw some light and provide the baseline data.

Objectives: To find out the incidence of adverse events following immunization among infants in District Srinagar.

Methods: It was a prospective study in which parents of infants receiving vaccines were contacted telephonically after specified time intervals to verify the occurrence of adverse events. The children were followed till 30 days of the administration of vaccines up to measles rubella vaccine.

Results: The incidence of AEFI reported in this study was 23.03% with 95% CI (22.24% to 23.85%). The most frequently reported AEFI was Fever (54.90%, n=1322), followed by Diarrhea (8.30%, n=200) and Vomiting (8.14%, n=196). AEFI were more in frequency during first week of receiving vaccine and most of the parents of children did not report AEFI after 7 days after vaccination.

Conclusions: This study reveals that most of the vaccines associated adverse reactions were of mild and non-serious type and rarely of serious nature, yet proper monitoring of vaccine associated adverse reactions; is too essential. Proper and complete reporting of AEFI's by field workers needs to be encouraged.

1. Introduction

Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease.[1] Immunization is one of the most effective public health interventions for protecting the individual and the public from vaccine-preventable diseases (VPDs). Immunization has saved millions of lives.[2] Vaccine is a biological substance that is administered to individuals to elicit immunity (protection) against a specific disease.[3] However, like other medicinal products, vaccines are not free from adverse reactions.[2] AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding, a symptom or a disease.[4] Vaccines used in National Immunization Program are said to be safe and effective. However, no vaccine is perfectly safe and adverse reactions may occur. In addition to the vaccines themselves, the process of immunization is a potential source of an adverse reaction.

Safety regarding vaccines has been questioned by many because of cases of AEFI reported at many places, but Smallpox and its Eradication will serve, above all, as an inspiring reminder of the knowledge and efforts that transformed smallpox from a universally dreaded disease to

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one the world could safely forget.[5,6] In 2012, Council for International Organizations of Medical Sciences (CIOMS) and WHO revised the existing classification of cause-specific categorization of AEFI and a new categorization was introduced.[4]

1. Vaccine product-related reaction.
2. Vaccine quality defect-related reaction.
3. Immunization related reaction (formerly Program Error").
4. Immunization anxiety-related reaction
5. Coincidental event

Based on seriousness and frequency vaccine reactions are classified into common (minor reactions) or rare (severe and serious reactions). Most vaccine reactions are minor and settle on their own.[7] The World Health Organization (WHO) advises on monitoring of adverse events following immunization against the target diseases of the Expanded Program on Immunization (EPI) and on implementation of safety surveillance in the monitoring of immunization programs. The WHO keeps a register of adverse reactions as part of the global drug- monitoring program.[8,9]

With the passage of time newer vaccines are being included in the National Immunization Program by Ministry of Health and Family Welfare Government of India, as such incidence and pattern of AEFI are expected to change. It has been observed that our health workers tend to under report or even hesitate to report non serious AEFI's also fearing disciplinary action from higher authorities and therefore the AEFI data from the routine immunization activities is poor and un reliable. Hence this study was conducted to throw some light and provide baseline data about the magnitude of Adverse Events Following Immunization among infants in District Srinagar.

2. Materials and Methods

2.1. Study design

A prospective study was conducted to estimate the incidence of adverse events following immunization among infants in District Srinagar. District Srinagar is the second most populous district of Jammu & Kashmir, situated in the centre of the Kashmir valley on the banks of river Jhelum. The study was done for a period of 18 months starting from 1^{st} May 2018 to 31^{st} October 2019. As such recruitment of all the new born infants for study was completed in 31^{st} September 2018 and each participant was followed for 13 months.

2.2. Study population

In our study, total of 871 newborn children were recruited from all health zones of District Srinagar.

2.3. Inclusion criteria

Newborn children belonging to District Srinagar enlisted for study in particular month, which could be followed up till one year and one month after measles vaccine.

2.4. Exclusion criteria

1. Children born in district Srinagar but belonging to other districts.
2. Those infants whose parents denied participation in the study.
3. Whose parents couldn't be communicated.

2.5. Study area

District Srinagar has four Health Zones and one Medical Block. New born children were recruited from all these health zones and a medical block.

2.6. Procedure

The study was conducted in District Srinagar of Jammu & Kashmir. All health zones of District Srinagar including medical block Hazratbal had a total population of 10,13,353 in 2018 as per records obtained from Chief Medical Office Srinagar office. As per the Sample Registration System Bulletin, September 2017 the birth rate in urban areas of Kashmir was 11.9 per 1000 population. The expected number of live births in Srinagar District in one year was expected to be 12,058. Hence the total number of expected live births in one month was estimated to be 1004 from all health zones of district Srinagar.

Particulars of pregnant females who were due for the date in the succeeding month were obtained from the RCH (Reproductive and Child Health) registers, as these registers were made available by concerned ASHAs (Accredited Social Health Activist) at the zonal headquarters (Primary Health Centre) on particular days as per their usual practice for validation of records etc. All such new born children who satisfied the inclusion criteria were included in the study. The recruited newborns were followed till thirteen months of age or one month after 1st dose of MR vaccine, which ever happened earlier? Since it was not operationally feasible to recruit all newborn children from District Srinagar simultaneously, recruitment of children was done in five phases one for each health Zone/Block. Once recruitment of children from one block/zone was done, the next Zone was taken up for recruitment of eligible children taking time line of the study in consideration.

Since this study is based on telephonic calls, consent was obtained from parent on telephone after introducing and explaining objectives of our study so that there were no apprehensions regarding the health of their children. The parents of the infants were interviewed telephonically regarding any occurrence of AEFI which was explained

to them through the checklist and additional information was also extracted from them regarding unusual symptoms. Telephonic interview of the parents of the children were conducted at Day-3 Day- 7 and Day-30 after receiving vaccine, as occurrence of AEFI was expected to be more during few days after receiving vaccine, less after one week and further decrease with passage of time, so follow up call was made at Day 30. Concerned ASHAs and MPHWs (Multi- purpose Health Workers) of our study area were contacted over phone to confirm about AEFI, reported by them, parents or guardians. Data regarding AEFIs from District Srinagar was accessed after obtaining necessary permission from Directorate of Health Services Kashmir.

3. Data analysis

Data was compiled and analyzed using Microsoft 2016 Excel spreadsheet. Descriptive statistics was computed to describe the socio-demographic characteristics of participants and to summarize the distribution of each of studied variables.

3.1. Ethical consideration

Ethical clearance was obtained from the institutional ethical committee before commencement of the study. The committee permitted the same as per protocol presented and described in the proposal vide no:199/ETH/GMC/ICM, dated 28/01/2018.

4. Results

A total of 871 newborn of District Srinagar were recruited from all the Health Zones of District Srinagar.

Table 1: Distribution of study population (newborns) (n=871)

Gender	Frequency	Percent
Male	450	51.7
Female	421	48.3
Birth Order		
≤ 2	729	83.7
>2	142	16.3
Mode of Delivery		
LSCS	669	76.8
Normal delivery	202	23.2
Birth Weight		
≤ 2.5 Kg	57	(6.54)
> 2.5 Kg	814	(93.46)
Gestational Age In Weeks		
≤ 37 Weeks	55	6.3
>37Weeks	816	93.7

5. Discussion

This prospective study was conducted for one and a half year and included 871 infants, although 1004 infants were expected to participate, but because of feasibility issue, exclusion criteria and time line of the study the sample taken was lower. The demographic profile and other indicators were comparable to SRS Bulletin 2017 and Census 2011 except the percentage of LSCS as shown in (Table 3) (76.8%) which was more than expected, and probably both because of preference of pregnant mothers to undergo surgery to avoid natural labour and also mushrooming of nursing homes offering delivery services. The incidence of AEFI reported in this study was 23.03% with 95% CI (22.24% to 23.85%). The most frequently reported AEFI was Fever (54.90%,), followed by Diarrhea (8.30%,) and Vomiting (8.14%,). In a study by Carrasco-Garrido et al in Spain, the rate was 14.6 per 1000 doses.[10] The reason for low incidence in that study could have been the passive survey done to find out the incidence of AEFI. Our study involved an active search for adverse events by contacting the care givers immediately following the vaccination of their children and thus we recorded a higher figure. Most frequently AEFI's were reported with OPV-2, LPV-2 (32.33%) (Table 2), followed by OPV-1, LPV-1 and f-IPV-1 (26.18%) (Table 3), MR-1 and Vitamin A (26.04%), OPV-3, LPV-3 and f-IPV-2 (18.78%) (Table 4), and the least with BCG, OPV-0 and Hepatitis-B (16.91%), as shown in Table 2. These results are consistent with most of the studies conducted throughout the world.[10,11] In our study the Pentavalent vaccine seems to be most implicated in causing fever than Hepatitis B as reported in literature and various other studies[11,12]. Refusal to breast feed was the most common AEFI reported (6.7%) up to day 3 after birth dose vaccines BCG, OPV-0 and Hepatitis B (Table 2). It may not be related to vaccine only and may be due to inadequate maintenance of temperature, bottle feeding and other causes of inadequate postnatal care. In our study BCG papule formation was very common 14.7%, as complained by parents when contacted after 30 days of receiving BCG vaccine and BCG Ulceration was complained by parents of 3.1% study children Table 2. Fever was seen to be very common (42%) after administration of vaccine at 6 weeks. There were similar AEFI at 10 weeks as those reported at 6 weeks but adverse events following immunization at 10 weeks were less in frequency as compared to AEFI at 6 weeks. AEFI 3 days after 10 week vaccine had decreased in comparison to AEFI 3 days after 6 week vaccine. Similar vaccines were given at 6 weeks OPV-1 + Pentavalent-1+ f-IPV 1 and 10 weeks of age OPV- 2 + Pentavalent-2. The reason could have been addition of f-IPV 1 given at 6 weeks age which resulted in significant increase of AEFI and rise of antibody titer after 4 weeks i.e., at 10 week vaccine otherwise AEFI were less as compared to 6 weeks vaccine. AEFI were more in frequency during first week of receiving vaccine and most of the parents of children did not report AEFI after 7 days after vaccination. Excessive crying, Fever and refusal to breast feeding were

Table 2: Distribution of AEFI from day 0 to day 30 following 0 dose of OPV, Hepatitis B and BCG

Type of Vaccine		**OPV-0 Hepatitis B BCG**		
Adverse Event	**Time Duration**	**0-3 days n(%)**	**4-7 days n(%)**	**8-30 days n(%)**
No Event		74(88.9)	739(84.9)	678(78.1)
BCG Pustule		0(0.0)	0(0.0)	128(14.7)
BCG Abscess		0(0.0)	0(0.0)	1(.1)
Fever		2(.2)	95(10.7)	7(.8)
BCG Injection Site discharge (Ulceration)		0(0.0)	0(0.0)	27(3.1)
Vomiting		0(0.0)	12(1.4)	17(2.0)
Refusal to Feed		59(6.7)	14(1.6)	2(.2)
Jaundice		31(3.6)	17(2.0)	0(0.0)
Respiratory Distress Syndrome		4(.4)	3(.3)	0(0.0)
Cyanosis		8(.9)	1(.1)	0(0.0)
Shock		0(0.0)	2(.2)	1(.1)
Communication Not Successful*		0(0.0)	0(0.0)	3(.4)

*Communication affected due to communication blockade in the valley following abrogation of Article 370 in J &K

Table 3: Distribution of AEFI from day 0 to day 30 following 1^{st} dose of OPV, LPV and f-IPV

Type of Vaccine		**OPV1 LPV1 f-IPV1**		
Adverse Event	**Time Duration**	**0-3 days n(%)**	**4-7 days n(%)**	**8-30 days n(%)**
No Event		390(45.0)	757(87.4)	799(92.3)
Fever		364(42.0)	38(4.4)	8(0.9)
Excessive Crying		61(7.0)	0(0.00)	0(0.00)
Diarrhea		45(5.2)	42(4.5)	31(3.6)
Vomiting		45(5.2)	20(2.3)	25(2.9)
Refusal to Feed		45(5.2)	16(1.8)	1(0.1)
Injection site swelling		0(0.00)	6(0.7)	0(0.00)
Injection Site redness		0(0.00)	2(0.1)	0(0.00)
Communication Not Successful*		6(0.7)	6(0.7)	6(0.7)

Table 4: Distribution of AEFI from day 0 to day 30 following 2^{nd} dose of OPV and LPV

Type of Vaccine		**OPV2 LPV2**		
Adverse Event	**Time Duration**	**0-3 days n(%)**	**4-7 days n(%)**	**8-30 days n(%)**
No Event		481(55.5)	797(92.0)	810(93.6)
Fever		354(40.9)	29(3.5)	4(0.5)
Vomiting		6(0.7)	18(2.0)	27(3.1)
Diarrhea		8(0.9)	20(2.3)	25(2.9)
Refusal to Feed		10(1.2)	4(0.5)	0(0.00)
Injection site swelling		0(0.00)	18(2.0)	0(0.00)
Excessive Crying		22(2.5)	2(0.2)	0(0.00)
Injection Site redness		0(0.00)	13(1.5)	0(0.00)
Communication Not Successful		8(0.9)	6(0.7)	6(0.7)

Table 5: Distribution of AEFI from day 0 to day 30 following 3^{rd} dose of OPV, LPV and 2^{nd} dose of f-IPV

Type of Vaccine		**OPV3 LPV3 f-IPV2**		
Adverse Event	**Time Duration**	**0-3 days n(%)**	**4-7 days n(%)**	**8-30 days n(%)**
No Event		567(65.5)	777(89.7)	815(94.1)
Fever		278(32.1)	52(6.0)	12(1.4)
Vomiting		3(0.4)	21(2.4)	20(2.3)
Refusal to Breast feed		0(1.2)	26(3.0)	10(1.2)
Diarrhea		1(0.1)	14(1.6)	10(1.2)
Rash		0(0.00)	0(0.00)	10(1.2)
Injection site swelling		0(0.00)	15(1.7)	0(0.00)
Excessive Crying		9(1.1)	1(0.1)	0(0.00)
Injection Site redness		0(0.00)	13(1.5)	0(0.00)
Non Responsive		0(0.00)	1(0.1)	0(0.00)
Communication Not Successful		10.1	9(1.0)	6(0.7)

Table 6: Overall distribution of AEFI as per their frequency

S No.	AEFI	Frequency	Percent (%)
1.	Fever	1322	54.90
2.	Diarrhea	200	8.30
3.	Vomiting	196	8.14
4.	Refusal to feed	192	7.97
5.	BCG papule	128	5.31
6.	Excessive crying	95	3.94
7.	Inj. site swelling	63	2.62
8.	General body rash	57	2.37
9.	Inj. site redness	52	2.16
10.	Jaundice	48	2.00
11.	BCG ulceration	27	1.12
12.	Cyanosis	09	0.37
15.	Shock	03	0.13
18.	BCG Abcess	01	0.04
	Total	2408	100

uncommon after one week. Fever was uncommon after one month of vaccination. Similar sequel was observed with further doses of vaccine at 14 weeks (OPV-3, Pentavalent-3 and f-IPV- 2) Table 5. When looking at the overall frequency of adverse events, Fever, vomiting, refusal to feed, diarrhea and injection site swelling were the most common events reported Table 6. Ambrish Gupta et al. from GSVM medical college Kanpur had also reported similar findings with fever being the most common adverse event. [13] The strength of the study was the longitudinal study design which allowed us to estimate the incidence of adverse events following immunization among infants in District Srinagar. There was clear information about pregnant mothers and their babies through MCTS numbers (Maternal and Child Tracking System). The limitation of our study was that it was confined to District Srinagar only while it should have been conducted on a larger population or should have covered all the districts of Kashmir valley to have a better idea in the area about the incidence. There was a communication blockade in the Kashmir valley in view of abrogation of Article 370/35A during some part of the study because of which all the parents couldn't be contacted during last phase of the study, however more than 50% of the participants were contacted and study results were not affected as revealed by the pattern observed throughout the course of the study.

6. Conclusion

This study reveals that most of the vaccines associated adverse reactions were of mild and non-serious type and rarely of serious nature, yet proper monitoring of vaccine associated adverse reactions; is too essential to prevent any kind of permanent damage or death. Proper reporting at field level should be appreciated in the form of incentives or providing appreciation certificates. On-going surveillance of adverse events following immunization, regular reporting and analysis of these data should be integral part of Immunization program and must be augmented where ever required.

7. Source of Funding

None.

8. Conflict of Interest

The authors declare that there is no conflict of interest.

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