Section: Pediatrics

Original Research Article

A STUDY TO ASSESS CLINICAL, LABORATORY, AND IMAGING PROFILE IN SEVERE AND SERIOUS ADVERSE EVENTS FOLLOWING IMMUNISATION IN A TERTIARY CARE HOSPITAL, TELANGANA

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ABSTRACT

Background: Vaccination is one of the most cost-effective child survival health interventions that prevents about 2 to 3 million deaths worldwide yearly [1]. No vaccine is entirely without risk and Adverse Events Following Immunization (AEFI) may occur [1] which can be detected through Post-market surveillance. A single serious adverse event following immunization (AEFI) or a cluster of events may lead to a loss of public confidence in the program and a major setback to immunization coverage. Based on the outcomes of the event, the World Health Organization (WHO) has classified AEFIs as Serious and Non-serious which is used for regulatory classification. The present study was taken up to study clinical, laboratory imaging profiles in severe AEFI in children from birth to 10years of age presenting at a tertiary care hospital in Telangana state. **Materials and Methods:** The study was conducted in the Department of Pediatrics, Niloufer hospital, affiliated to Osmania Medical College. It is the largest tertiary care center in the state of Telangana, situated in the heart of Hyderabad. This is a Hospital based cross sectional observational study conducted from November 2020 - November 2022.A total of 95 children with 290 doses of different vaccines as per Universal Immunization Schedule with severe and serious adverse events following immunization (AEFI) presenting to hospital from birth to 10 years of age were included In the study. Detailed history about immunization taken, clinical, laboratory and imaging profiles and outcome of all the children were evaluated. **Result:** Among 95 children from Birth to l0 years of age, admitted with severe and serious AEFI in Niloufer Hospital during the study period, majority were between 13-24 months(28.42%),and between the age of 1-2 months (23.16%). A total of 290 doses of different vaccines were administered to 95 study participants. Majority of severe AEFI were observed after administration of oral vaccines (42.76%), followed by intra muscular vaccines (31.38%). Of all OPV was the most common vaccine responsible for severe AEFI (26.21%) followed by the Pentavalent vaccine (19.31%), Rota virus vaccine (16.55%). MR and IPV (12.76%) each. DPT contributed to 11.38% of total doses. In this study, majority with severe and serious AEFI reported within 12-24 hours (62%). In this study we found most of severe AEFI was high grade fever and serious AEFI was seizures (74.74%). Among the study population, lab investigation showed CRP was positive in 14.74%. and the fever profile was negative in all. All the imaging studies were normal, except one MRI which revealed Guillian barre syndrome, and one NSG scan showed Sub Dural hematoma. In the study population, mortality reported was 5.26%.Out of 95 study population, 5 children died,Of which four were of 2-3 months, one child of 18 months. Three presented post first dose of Pentavalent, OPV, Rota vaccine, IPV. One presented post third dose of Pentavalent, Rota vaccine, IPV-2. One presented after first booster dose of DPT, OPV, MR-2. Four children presented within 24 hrs of immunization with complaints, one child presented after 2 days of immunization. All five presented

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with fever followed by seizures. **Conclusion:** The incidence of severe and serious AEFI (90 per 290doses), mortality (5 per 290 doses) in the present study. The study revealed that the vaccines were safe and well-tolerated as the majority (95%) of the children recovered well in 3-5 days after admission. The serious AEFI leading to mortality incidence is less.Hence awareness among health professionals and the public regarding reporting of AEFI should be continued to increase the safety profile of vaccines, and to increase public trust in immunization programs.

INTRODUCTION

Adverse event following immunization (AEFI) is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of the vaccine(1).

Adverse Events following immunization (AEFI) are an important aspect of public health surveillance and patient safety in immunoprophylaxis programs. These reactions can vary from minor, such as local pain at the injection site, to severe, such as anaphylactic shock.[1-5]

To address the issue of underreporting the WHO therefore instituted the Global Vaccine Safety Initiative, which set out indicators primarily for monitoring case reporting.[6-9] A case reporting target of 10 AEFI per 100,000 surviving infants per year was set in the Global Vaccine Action Plan (GVAP) to monitor the performance of AEFI surveillance systems.[10]

In 2015, the average reporting rate was 549 AEFI per 100,000 surviving infants globally. The number of countries that reported rates greater than 10 per 100,000 surviving infants also increased from 8 (4%) in 2000 to 81(42%) in 2015.[11]

AEFIs can be common and minor (like fever, local pain, and swelling), severe (like pain and swelling which spreads beyond the nearest joint, high-grade fever), and serious AEFIs (conditions requiring hospitalization or leading to death or disability).

Types of AEFIs by severity and frequency

Common minor AEFIs

Severe AEFIs

Serious AEFIs

Severe AEFIs and serious AEFIs: An AEFI will be considered serious if it results in death, results in persistent or significant disability/ incapacity or a cluster (two or more cases) of AEFIs occur in a geographical area.

AEFIs that are not minor but do not result in death or disability are categorized as severe. Severe is used to describe the intensity of a specific event (as in mild, moderate or severe).

The present study was taken up to study clinical, laboratory and imaging profiles in severe AEFI in children from birth to 10years of age presenting at a tertiary care hospital in Telangana state.

MATERIALS AND METHODS

In this study 95 children presenting with severe and serious Adverse Events Following Immunization (AEFI) from birth to 10 years of age during the study period from November 2020 – November 2022 satisfying the inclusion criteria were enrolled into the study after getting informed consent from the parents /guardians and ethical committee clearance.

The present study was a hospital based cross sectional observational study to assess clinical, laboratory, and imaging profile in severe and serious adverse events following immunization .This study is conducted in the Department of Pediatrics, in a tertiary care hospital, Niloufer hospital, Hyderabad, Telangana.

Inclusion Criteria

- Age group between birth – 10 years
- Both genders
- History of immunization
- Parents/guardians of children with the above mentioned criteria who are willing to give informed consent.

Exclusion Criteria

- Children >10 years of age.
- Age group between birth – 10 years, with pre-existing illness like nephrotic syndrome, HIV, or immune suppression.
- Infective, metabolic, structural malformations causing seizures were excluded.
- Parents or guardians those who are not willing to give informed consent.

A detailed history for every case was taken from the parent/guardian.

The following investigations were done after complete clinical examination.

- Complete blood picture
- Renal function tests with Serum electrolytes
- Serum Calcium,
- C-Reactive protein,
- Random blood sugar,
- Complete urine examination,
- Urine for metabolic profile,
- Fever profile,
- Neuro sonography,
- CT Scan /MRI scan
- Infants/Children were followed till they were discharged.
- Investigations, and disease course were documented.

Statistical Analysis: The data was entered in Microsoft Excel 2010 version. Data was analyzed using Microsoft Excel 2010 and Epi Info 7.2.0.

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Descriptive and inferential statistical analysis were used in the present study. Results on continuous measurements were presented on Mean ± SD (Min-Max) and results on categorical measurements were presented in Number.

RESULTS

Among the study population, 28.42% were between 13-24 months, 23.16% were between the age of 1-2 months, 20% were between the age of 4-6 months, 8.42% were between the age of 3 months, 10-12 months each. 7.37% were between age of 7-9 months. 4.21% were above the age of >24 months.

Table 1: Table showing the age distribution

Age distribution	Frequency	Percentage
1-2 months	22	23.16
3 months	8	8.42
4-6 months	19	20.00
7-9 months	7	7.37
10-12 months	8	8.42
13-24 months	27	28.42
>24 months	4	4.21
Total	95	100.00

Table 2: Distribution of AEFI rate per 290 doses according to vaccines administered.

Name of the vaccine	Frequency	Percentage
BCG	1	0.34
DPT -I	30	10.34
OPV -I	45	15.52
MR -II	27	9.31
MR-I	10	3.45
DPT -II	3	1.03
PCV	2	0.69
Penta I	21	7.24
Rota I	14	4.83
IPV -I	9	3.10
Penta II	7	2.41
OPV II	6	2.07
Rota II	6	2.07
Penta III	28	9.66
IPV II	28	9.66
OPV III	25	8.62
RV III	28	9.66
Total	290	100.00

Table 3: characteristics of mortality

Parameter	Sub group	Frequency
Age	2-3 months	4
	18 months	1
Gender	Male	3
	Female	2
Vaccines	Pent I/OPVI/Rota I/IPV I	3
	Pent III/OPVIII/Rota III/ IPV II	1
	DPT I/MR II/OPV booster	1
Duration between and admission event	<24 hours	4
	2 days	1
Clinical features	Fever followed by seizures	5
Cause of death	Respiratory failure	5
Time of death	Day 1 of admission	2
	Day 2 of admission	2
	Day 3 of admission	1

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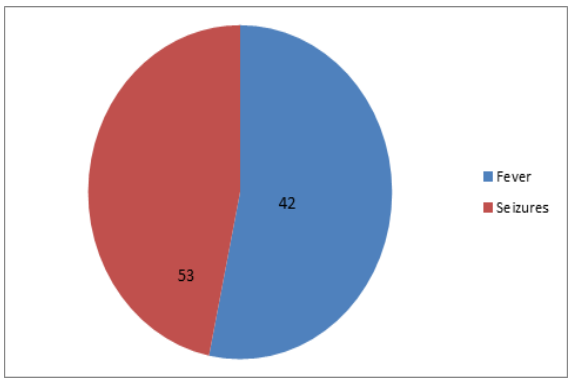

Figure 1: Distribution of AEFI in children according to gender

[Figure 1] showing AEFI in children according to gender.

Among the study population, 44.21% were males and 55.79% were females.

In the present study, among the study population, majority of severe AEFI were observed after administration of OPV (26.21%) followed by pentavalent vaccine (19.31%), rota virus vaccine (16.55%). MR and IPV were administered 12.76% each. DPT doses were 11.38% of total doses.

[Figure 2] showing the duration between vaccine adminstration and admission

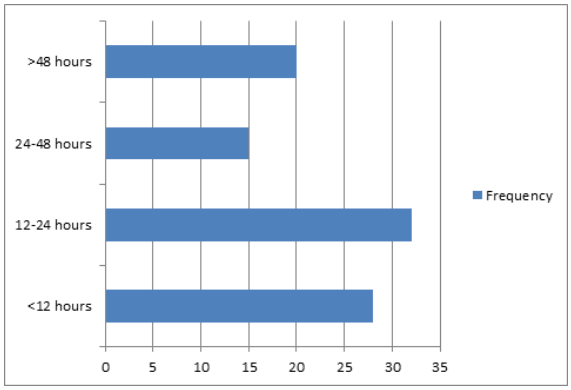

Figure 2: Duratuion from the event to hospital admission

Among the study, the majority (33.68%) of the admissions were between 12-24 hours, 29.47% were admitted within 12 hours, and 21.05% were admitted >48 hours. 15.75% were admitted between 2-48 hours.

[Figure 3] showing the clinical features

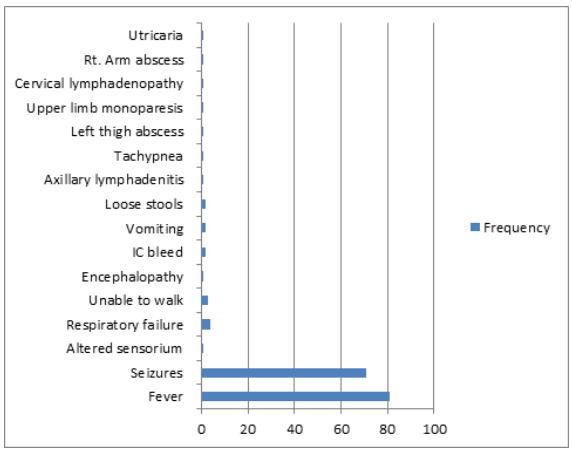

Figure 3: clinical features

Among the study population, the majority of them had a fever (85.26%), followed by seizures (74.74%). 36.84% had Hb below 10 gm%. Rest of them had above 10 gm%.

Fever profile was negative in all.

Bacterial culture was sterile in all the ones where it was done.

All the imaging studies were normal, except one MRI which revealed Guillain barre syndrome, and one NSG scan showed Subdural hematoma.

Among the study population, 5.26% was the mortality.

DISCUSSION

The present hospital-based cross-sectional study was done in the Department of Pediatrics, at a tertiary care center in the state of Telangana. A total of 290 doses of different vaccines were administered to 95 study participants as per Universal Immunisation Schedule .

Immunization is an important public health intervention for improving child health by reducing morbidity and mortality due to vaccine-preventable diseases. Although vaccines are safe, they are not completely risk-free and adverse events may occasionally occur. Irrespective of the nature, minor or major, adverse events can cause anxiety and lead to loss of public trust in the Universal Immunization Programme. The present work is done to study clinical, laboratory and imaging profiles of severe and serious AEFI in children from birth to 10years of age presenting at a tertiary care hospital.[12-17]

Among the study population, majority of severe AEFI were observed among the age group of 13-24 months (28.42%) and 1-2 months(23.16%) comparable with study of Pagar VS et al.[12]

Majority of severe AEFI were observed after administration of oral vaccines (42.76%), followed by intra muscular vaccines (31.38%).

Of all OPV was the most common vaccine responsible for severe and serious AEFI (26.21%) followed by the Pentavalent vaccine (19.31%), Rota virus vaccine (16.55%). MR and IPV 12.76% each.

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DPT contributed to 11.38% of total doses comparable with study of Pagar VS et al.[12]

In the study, majority with severe and serious AEFI reported within 12 hours (29.47%) of immunization and 12-24 hours (33.68%) comparable with Sugawara T et al.[13]

In this study we found majority severe AEFI were high grade fever(85.26%) and serious AEFI were seizures (74.74%) associated with fever.

Among the study population lab investigation showed CRP was positive in 14.74%. and the fever profile was negative in all.

All the imaging studies were normal, except one MRI which revealed Guillene bar syndrome, and one NSG scan showed Sub dural hematoma.

Among the study population mortality reported was 5.26%. out of 95 study population, 5 children died, Of which four were of 2-3 mnths, one child of 18 months. Three presented post first dose of Pentavalent, OPV, Rota vaccine, IPV.

one presented post third dose of Pentavalent, Rota vaccine, IPV-2. One presented after first booster dose of DPT, OPV, MR-2. Four children presented within 24 hrs of immunization with complaints, one child presented after 2 days of immunization. All five presented with fever followed by seizures.[18-20]

CONCLUSION

The incidence of severe and serious AEFI (90 per 290doses), mortality (5 per 290 doses) in the present study. The study revealed that the vaccines were safe and well-tolerated as the majority (90%) of the children with severe and serious AEFI recovered well in 3-5 days after admission. The serious AEFI leading to mortality is less. Hence awareness among health professionals and the public regarding reporting of AEFI should be continued to increase the safety profile of vaccines, and to increase public trust in immunization programs.

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