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Original Research Article

Adverse events following immunization with pentavalent vaccine in a tertiary care hospital

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ABSTRACT

Background: Immunizations currently save 3 million lives per year throughout the world and is one of the most cost-effective health interventions. The Global Alliance for Vaccines and Immunizations (GAVI) and WHO recommended the use of pentavalent to replace the DPT vaccine in developing countries. Vaccines related most side effects are mild and non-serious. Surveillance of adverse events following immunization will enable us to monitor the safety of immunization programs and thereby contribute to validating the immunization program. The main aim of this study is to analyze all suspected adverse events in children reported for pentavalent vaccination.
Methods: A prospective, observational epidemiological study was conducted in the department of Paediatrics OPD at tertiary care teaching institute during October 2016 to December 2016. The study was conducted amongst 190 children attending the department of Paediatrics OPD for the second or third dose of pentavalent vaccine.
Results: The study shows the following adverse effects after pentavalent injection 127 (66.8%) children had pain at the site of injection, 103(54.2%) mild fever, Swelling at injection site 84(44.2%) and 55(28.9%) children held their leg back due to pain. In majority 85 (44.7%) of children antipyretic and in 65 (34.2%) children analgesic was given was given to relieve the symptoms. The parents were very positive for completing their children's immunization schedule even though they have faced few symptoms.
Conclusions: It can be concluded that all the adverse events reported were mild and could be managed easily without any complications.

Keywords: Adverse effects, DPT, Immunization, Pentavalent

INTRODUCTION

It has been estimated that under Universal Immunization Programme (UIP), 2.7 crore children are eligible for receiving vaccines in our country.[1] Immunizations currently save 3 million lives per year throughout the world and are one of the most cost-effective health interventions that exist. Indeed, the majority of the population considers immunization to be an extremely important measure that parents can take to keep their children well, and one that is of great benefit to the community.[2]

Pentavalent vaccine is a combination vaccine which protects against five preventable diseases those are Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B. The Global Alliance for Vaccines and Immunizations (GAVI) and WHO recommended the use of this pentavalent vaccine in developing countries to replace the DPT vaccine.[3]

Immunization of the paediatric population prevents and protects the population from serious diseases; however, administration of vaccines to healthy children also involves risks of adverse events. More than 3 million

children in developing countries die each year from vaccine-preventable diseases such as measles, diphtheria and polio.[4]

The World Health Organization recommends that routine infant immunization programs include a pentavalent vaccine. The immunogenicity and safety of pentavalent vaccine were assessed in four clinical trials and a large post-marketing surveillance study. Pentavalent vaccination was found to be highly immunogenic in each of the primary vaccination studies and was also shown to be suitable as a booster with the advantage that it could be given concomitantly with measles vaccine. The India Ministry of Health and Family Welfare introduced pentavalent DTP vaccines in the UIP with the aim of reducing the burden of Hib-related morbidity and mortality in April 2008.[5] Vaccines like other pharmaceutical product are not entirely risk-free; while most side effects are mild and non-serious. So, the vaccine safety is much higher than the drugs.[6]

Safety regarding vaccines had been questioned because of cases reported at many places.[7] As a result; certain misconceptions about the safety of the vaccines have arisen in many communities. Vaccine unacceptance by publics may hamper the success of an immunization programme.[8] Pharmacovigilance on vaccines in India is still in cradle stage. There is a need of pharmacovigilance of vaccines on a large scale in India. As only a few Indian studies on adverse reactions to vaccines could be traced, we wished to collect data on AEFI in the pediatric population of India through the present study.[9]

Public trust in newly introduced vaccines can be strengthened by monitoring vaccine safety. Surveillance of adverse events following immunization will enable us to monitor the safety of immunization programs and thereby contribute to validating the immunization program. In this way, the undesirable adverse events of the immunization program can be effectively managed, and any inappropriate measures based on reports of adverse effect that may cause concern in society can be prevented.[10] The main aim of this study is to analyze all suspected adverse events in children reported for pentavalent vaccination.

METHODS

A prospective, observational epidemiological study was conducted in the department of Paediatrics OPD at tertiary care teaching institute during October 2016 to December 2016. The children were accompanied by parent or guardian who, after giving his/her informed oral consent, agreed to take part in the study. Each child's details were recorded in the predesigned and pretested questionnaire. The parents/guardians of children were also given telephone number of doctors so that they could contact them in case of any problem following vaccine administration. All the children attending the department of Paediatrics OPD for the second or third dose of pentavalent vaccine were included in the study. A total of 190 children were enrolled in the study. Informed consent was taken from the parents attending along with the children. The parents were explained about the purpose of the study and data was collected by personal interviews.

Inclusion criteria

- Children attending Immunization OPD for second or third dose of pentavalent vaccine.
- Parents giving consent and ready to participate in the study

Exclusion criteria

- Children attending Immunization OPD for the first dose of pentavalent vaccine.

RESULTS

Table 1 shows that after pentavalent injection 127 (66.8%) children had pain at site of injection, 103 (54.2%) children got mild fever, swelling at injection site 84 (44.2%), Redness at site of injection 72 (37.8%) and 55 (28.9%) children held their leg back due to pain while making movements.

Table 1: Number and type of adverse events.

Type of sign/symptom	No. of children	%
Pain at site of injection	127	66.8
Fever	103	54.2
Swelling at injection site	84	44.2
Redness at site of injection	72	37.8
Held the leg back due to pain	55	28.9
Unusual crying	51	26.8
Nodule formation	23	12.1

Table 2 shows that following were the management modalities of the adverse effect by the parents, in majority children 85 (44.7%) antipyretic was given, in 65 (34.2%) analgesic was given was given, 42 (22.1%) parents consulted doctors while, 57 (29.9%) parents applied hot or cold fomentation and 17 (8.9%) applied some herbal products to relieve the symptoms.

Table 2: How the adverse events were managed.

Management	No. of children	%
Antipyretic was given	85	44.7
Analgesic was given	65	34.2
Consulted back to doctor	42	22.1
Hot fomentation	30	15.7
Cold fomentation	27	14.21
Did nothing as it was expected	23	12.1
Other herbals were applied	17	8.9

Table 3 shows that parents are very positive for completing their children's immunization schedule even though they have faced few symptoms. They replied that 175 (92.10%). Doctors always support them in the process of immunization, 171 (90.00%) confirmed that they will complete the schedule irrespective of these symptoms as these symptoms are transient and easily manageable and 165 (86.84%) said that the Immunization is more beneficial to their children in comparison to adverse effects.

Table 3: Attitude towards further immunization schedule.

Attitude	No. of parents	%
Doctors are always in support	175	92.10
Will continue with further schedule	171	90.00
Immunization is more beneficial as compared to AR	165	86.84
The symptoms are manageable	144	75.78

DISCUSSION

The present study a prospective, observational epidemiological study was conducted in the department of Paediatrics OPD at tertiary care teaching institute during October 2016 to December 2016. All the children attending the department of Pediatrics OPD for the second or third dose of pentavalent vaccine were included in the study. A total of 190 children were enrolled in the study. The main aim of this study is to analyze all suspected adverse events in children reported for pentavalent vaccination.

In the present study it was observed that after pentavalent injection 127 (66.8%) children had pain at site of injection, 103 (54.2%) children got mild fever, swelling at injection site 84 (44.2%), redness at site of injection 72 (37.8%) and 55 (28.9%) children held their leg back due to pain while making movements.

In the present study it was observed that following were the management modalities of the adverse effect by the parents, in majority children 85 (44.7%) antipyretic was given, in 65 (34.2%) analgesic was given was given, 42 (22.1%) parents consulted doctors while 57 (29.9%) parents applied hot or cold fomentation and 17 (8.9%) applied some herbal products to relieve the symptoms.

In the present study we found that post pentavalent vaccination there was no major adverse event and this is similar to findings by Kompally V et al, while in contrast to the findings of the study by Puliey J et al his study reported that pentavalent vaccine is doing harm, he noticed 8 deaths in Bhutan.[6,11] In the present study, it was observed that our study has similar results with the Kompally V et al study which was conducted in 2016.[6] This study reported only mild adverse events such as fever; unusual crying, swelling and no serious adverse events were recorded.

In a study by Joshi ND et al found that of a total sample of 4320 children, ranging in age from 0 to 14 years, 10110 vaccine doses were given.[9] Each child received 2.34 vaccines on an average. Out of 4320 children, 899 children (20.8%) suffered 1003 AEFI. The most frequent types of adverse reactions to vaccines were fever (34.33 per 1000 doses), excessive crying (30.95 per 1000 doses) and injection site swelling (18.57 per 1000 doses). AEFI rate per 1000 doses was 99.2%. They also found no major adverse reactions. Similar results were observed by Karami M et al.[10] The cumulative incidence rate of pentavalent-related adverse events during 48 h following immunization was estimated to be 15.8% for swelling, 10.9% for redness, 44.2% for pain, 12.6% for mild fever, 0.1% for high fever, 20.0% for drowsiness, 15.0% for loss of appetite, 32.9% for irritability, 4.6% for vomiting and 5.5% for persistent crying. There is no evidence for the occurrence of convulsion and encephalopathy among children who receive pentavalent vaccines. Similar results were observed by Ahmad S et al.[12] A total of 230 infants participated during the study period. The incidence of minor adverse events reported very high, 67 per 100 doses across all doses. Fever was most common symptom reported. Demographic character or birth history of the infant had not shown an effect on the occurrence of any adverse event. Similar results were observed by Karami M et al.[10] The cumulative incidence rate of pentavalent-related adverse events during 48 h following immunization was estimated to be 15.8% for swelling, 10.9% for redness, 44.2% for pain, 12.6% for mild fever, 0.1% for high fever, 20.0% for drowsiness, 15.0% for loss of appetite, 32.9% for irritability, 4.6% for vomiting and 5.5% for persistent crying. There is no evidence for the occurrence of convulsion and encephalopathy among children who receive pentavalent vaccines.

In the present study, it was observed that parents are very positive for completing their children's immunization schedule even though they have faced few symptoms. They replied that 175 (92.10%) Doctors always support them in the process of immunization, 171 (90.00%) confirmed that they will complete the schedule irrespective of these symptoms as these symptoms are transient and easily manageable and 165 (86.84%) said that the Immunization is more beneficial to their children in comparison to adverse effects. These results are very inspiring and prove that the present health system is working in a right direction to increase the immunization coverage. Similarly, in a study by Maria Anna Coniglio et al of the 1,500 selected parents, 81.0% participated in the study.[13] Prior to the survey, the majority of children (97.6%) received recommended vaccines. Most parents (74.4%) received information about vaccinations from Family Paediatricians, showed a good knowledge about the side effects of the vaccines (73.1%), did not worry about their potential dangerousness (53.0%) and would

have accepted their children to be vaccinated even if it was not required for daycare (84.1%). The majority (79.9%) were not disposed to follow the advices of the anti-vaccination movements. In a study by Santos et al they found that the progress of the cases of AEFI consisted of cure without sequelae in 807(99.6%) cases.[14] One case, classified as severe and/or unusual event, evolved to cure with sequelae; two cases, classified as the fever higher than 39.5˚C and local cold abscess, had not recorded the progress. A major limitation is that we do not know to which extent the causality of these adverse events following pentavalent immunization can be confirmed. Present study has small sample size, and information about adverse events was noted after one month of administration of the vaccine.

CONCLUSION

It can be concluded from our study that all the adverse events reported were mild and could be managed easily without any complications. As our study did not find any deaths for pentavalent vaccination, we conclude that pentavalent vaccine can be given safely.

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