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ORIGINAL ARTICLE

ADVERSE EVENTS FOLLOWING PENTAVALENT VACCINE ADMINISTRATION: A DESCRIPTIVE STUDY IN THE INDIAN CONTEXT

Kejadian Ikutan Pasca Imunisasi (KIPI) Setelah Pemberian Vaksin Pentavalen: Studi Deskriptif dalam Konteks India

Roop Sharma[1], Bhanupriya Sharma[2], Yashu Saini[3], Ramesh Bairwa[4], Munish Kakkar[4]
[1]Associate Professor, Mahatma Gandhi Medical College, Jaipur, India, 302022, roopksharma@gmail.com
[2]Resident, Mahatma Gandhi Medical College, Jaipur, India, 302022, bhanupriyasharma536@gmail.com
[3]Associate Professor, Mahatma Gandhi Medical College, Jaipur, India, 302022, dryashusaini79@gmail.com
[4]Assistant Professor, Mahatma Gandhi Medical College, Jaipur, India, 302022, dr.rameshbairwa@gmail.com
[5]Professor, Mahatma Gandhi Medical College, Jaipur, India, 302022, mkkakkar15@gmail.com
Corresponding Author: Roop Sharma, roopksharma@gmail.com, Mahatma Gandhi Medical College, Jaipur, 302022, India

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ABSTRACT
Background: Immunization is one of the best ways to prevent childhood diseases. The pentavalent vaccine protects against five serious illnesses with fewer injections. It is cost-effective and usually causes fewer adverse events following immunization (AEFI). However, there are still limited data on AEFI after giving the pentavalent vaccine, compared to giving the DPT, Hep-B, and Hib vaccines separately. **Purpose:** To determine the proportion and factors associated with adverse events following immunization with pentavalent vaccines. **Methods:** This was a descriptive study conducted at an immunization clinic in a tertiary care center in India between January 2023 and December 2023. The study population consisted of all infants attending the clinic for vaccination, and all eligible infants receiving pentavalent vaccines were included in the study. The study was done to understand the frequency and type of AEFIs and to ensure the vaccine safety. **Results:** A total of 93 infants were included in this study, and 264 adverse events were noted in our study. Fever was the most common presenting adverse effect (22.73 %), other adverse effects were pain at injection site (21.21%), swelling at injection site (15.53%), redness at site of injection (14.39%), 10.60% held their leg back due to pain, persistent crying (9.47%) and abscess formation (4.55 %.), and seizures (1.52%). **Conclusion:** Most of the adverse effects observed in present study were of mild nature and of non-serious type. No major AEFI or permanent damage was noted in our study. The benefits of vaccination far outweigh the risks.

ABSTRAK
Latar Belakang: *Imunisasi adalah salah satu cara terbaik untuk mencegah penyakit pada anak-anak. Vaksin pentavalen memberikan perlindungan terhadap lima penyakit serius dengan jumlah suntikan yang lebih sedikit. Vaksin ini efektif dari segi biaya dan biasanya menyebabkan*

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kejadian ikutan pasca imunisasi (KIPI) yang lebih sedikit. Namun, data mengenai KIPI setelah pemberian vaksin pentavalen masih terbatas, jika dibandingkan dengan pemberian vaksin DPT, Hep-B, dan Hib secara terpisah. ***Tujuan:*** *Menentukan proporsi dan faktor-faktor yang berhubungan dengan kejadian ikutan pasca imunisasi setelah pemberian vaksin. pentavalen.* ***Metode:*** *Ini adalah studi deskriptif yang dilakukan di klinik imunisasi di pusat layanan kesehatan tersier di India antara Januari 2023 hingga Desember 2023. Populasi penelitian terdiri dari semua bayi yang datang ke klinik untuk imunisasi, dan semua bayi yang memenuhi syarat dan menerima vaksin pentavalen diikutsertakan dalam penelitian ini. Penelitian ini dilakukan untuk memahami frekuensi dan jenis KIPI serta untuk menjamin keamanan vaksin.* ***Hasil:*** *Sebanyak 93 bayi diikutsertakan dalam penelitian ini, dan tercatat 264 kejadian ikutan. Demam merupakan efek samping yang paling umum (22,73%). Efek samping lainnya meliputi nyeri di lokasi suntikan (21,21%), bengkak di lokasi suntikan (15,53%), kemerahan di lokasi suntikan (14,39%), menarik kaki karena nyeri (10,60%), menangis terus-menerus (9,47%), pembentukan abses (4,55%), dan kejang (1,52%).* ***Simpulan:*** *Sebagian besar efek samping yang diamati dalam penelitian ini bersifat ringan dan tidak serius. Tidak ditemukan KIPI berat atau kerusakan permanen dalam penelitian ini. Manfaat vaksinasi jauh lebih besar dibandingkan risikonya.*

INTRODUCTION

Immunization stands as the most effective method for preventing childhood diseases, and significant achievements have been made in preventing and controlling the vaccine preventable diseases (VPDs) by the Government of India after the implementation of Universal Immunization Program (UIP) (1–3). It is estimated that vaccination prevented more than 37 million deaths worldwide between 2010 and 2019 (4). Continuous efforts are needed to strengthen routine immunization. The full immunization coverage was 76.48% in the year 2019-2021, as per NFHS-5, as compared to 62% in 2015-16. The Universal Immunization Program decided to introduce pentavalent vaccine in selected states viz. Kerala and Tamil Nadu in December 2011. Currently, pentavalent vaccine has been expanded to all 36 states, under UIP (5).

According to the UIP, each infant will receive three doses of pentavalent vaccine at week 6, week 10 and week 14 of life (3). The pentavalent vaccine is a combination vaccine given to infants as part of routine immunization. It protects against five serious diseases: diphtheria, pertussis (whooping cough), tetanus, hepatitis B, and Haemophilus influenza type b (Hib). Instead of giving separate shots for each disease, the pentavalent vaccine delivers protection through a single injection. Under India's Universal Immunization Program, this vaccine is given in three doses at 6, 10, and 14 weeks of age (3,5).

In addition to quick and safe immunity, the pentavalent vaccine reduces cost, occupational and environmental hazards, and causes less distress for children and their parents (6). The World Health Organization (WHO) and the Global Alliance for Vaccine and Immunizations (GAVI) have recommended this pentavalent vaccine in routine infant immunization programs. However, despite the positive impact of pentavalent vaccination, concerns remain about potential adverse effects. Adverse events following immunization (AEFI) are usually mild but may on rare occasions be life-threatening. The majority of serious events reported after immunization are coincidences and there is no causal relationship between the vaccine and the reported event (7).

At times, however, these are caused by the vaccine or by an error in the administration or handling of the vaccine. Adverse events following immunization (AEFI) are well-documented with separate DPT, Hep-B, and Hib vaccines in various studies (8). However, data on AEFI with pentavalent vaccine, which combines these vaccines, are still limited. It is important to determine if there is a reduction in the proportion of minor and major AEFI after pentavalent vaccination compared to separate vaccines. The potential causal association between pentavalent vaccine and AEFI, or the coincidental occurrence of

adverse events, needs to be evaluated. Monitoring the reactogenicity of vaccines used in the immunization program is crucial. To maintain public trust in the immunization program, it is essential to identify, detect, prevent, and appropriately communicate AEFI (9).

AEFIs are any undesirable medical condition that occurs after vaccination (10). AEFIs can be classified into two categories: serious and non-serious. Serious adverse events are those that require hospitalization or result in permanent disability, while non-serious adverse events are usually mild and self-limiting. Like all vaccines, pentavalent vaccine can cause adverse events in some individuals (11). However, the occurrence of AEFIs is usually rare, and the benefits of vaccination far outweigh the risks. This observational study was conducted to examine adverse events following immunization (AEFI) with the pentavalent vaccine. Infants were closely monitored to understand how often these events occurred and whether any factors—such as birth weight, gestational age, or delivery type—were linked to them. The main goal was to better understand the safety profile of the pentavalent vaccine in real-world conditions and to provide useful data for strengthening immunization practices in India.

METHODS

This descriptive study was conducted in the pediatric outpatient department (OPD) of a tertiary care center, from January 2023 to December 2023. Infants attending the pediatric OPD for routine pentavalent vaccine immunization were enrolled after obtaining informed verbal consent from their parents. A consecutive sampling technique was used. All eligible infants who received pentavalent vaccination during the study period and whose parents gave verbal consent were included. A total of 93 infants participated in the study. Adverse events occurring at any of the three doses were recorded. Infant details were documented in a pre-designed questionnaire covering demographic information, vaccination history, allergy history, and more. Parents were provided with the hospital's contact number to report any issues following immunization.

Parents were thoroughly informed about the purpose of the study. Completed proformas were returned by parents during the next scheduled vaccination visit. Infants were excluded if parental consent was not given or if a scheduled vaccine dose was missed during the observation period. Ethical clearance was obtained from the institutional ethical committee (MGMC & H/IEC/2022/1003), at Mahatma Gandhi Medical College. Data were entered into Microsoft Excel and analyzed using basic descriptive statistical methods. Categorical variables such as sex, mode of delivery, birth weight, and types of adverse events were presented as frequencies and percentages. No advanced statistical tests were applied, as the study's primary objective was to describe the pattern and proportion of adverse events following pentavalent vaccination.

RESULTS

In total 93 infants attending the pediatric OPD for vaccination were enrolled in this study after taking verbal informed consent from the parents, Table 1 shows the characteristics of study subjects, 51.61% were male and 48.39% were female. There were higher rates of caesarean section (58.06%) and 11.83% were low birth weight and 46.24% were preterm.

A total of 264 adverse events were reported following pentavalent vaccination in our study. Based on Table 2, the most frequently observed symptom was fever, reported in 22.73% of cases, defined as an axillary temperature greater than 99°F. Other commonly reported symptoms included pain at the injection site (21.21%), swelling (15.53%), and redness (14.39%), all of which were categorized as mild reactions. Additionally, 10.60% of infants were observed to hold their leg back during movement, potentially due to localized discomfort. Excessive crying occurred in 9.47% of the cases, and abscess formation at the injection site was noted in 4.55%. Seizure episodes were rare, occurring in 1.52% of infants. Among those, three children experienced seizures within four hours of vaccination, while one child exhibited abnormal movements after 24 hours.

Overall, most adverse events observed were mild and self-limiting, indicating a favorable short-term safety profile of the pentavalent vaccine. Figure 1 depicts all adverse events post pentavalent vaccination.

Table 1
Characteristics of Study Group

Clinical Profile	n	%
Sex		
Male	48	51.61
Female	45	48.39
Birth Order		
≤ 2	59	63.44
>2	34	36.56
Mode Delivery		
Caesarean section	54	58.06
Normal delivery	39	41.94
Birth Weight		
≤ 2.5 kg	11	11.83
>2.5 kg	82	88.17
Gestational Age in Weeks		
≤ 37 weeks	43	46.24
>37 weeks	50	53.76

Table 2
Type of Adverse Events After Pentavalent Vaccination

Presenting Complaints	n	%
Within 24 Hours		
Fever	60	22.73
Pain at injection site	56	21.21
Swelling at injection site	41	15.53
Redness at site of injection	38	14.39
Held the leg back due to pain	28	10.60
Inconsolable cry	25	9.47
Abscess formation	12	4.55
Seizure	3	1.13
After 24 Hours		
Seizure	1	0.37

DISCUSSION

This was a descriptive study in which infants were monitored for any adverse events following their immunization with the pentavalent vaccine. The findings of this study indicate that pentavalent vaccination is generally safe, with most adverse events being mild and self-limiting. Serious outcomes such as seizures were rare and did not result in hospitalization. These results are consistent with previous studies and provide additional local evidence supporting the continued inclusion of the pentavalent vaccine in the national immunization schedule. Rare and severe AEFIs have been reported following pentavalent vaccination (12,13). These include anaphylactic shock, seizures, encephalopathy, and even death.

In this study, we found that fever is the most common complication following pentavalent vaccination, occurring in 22.73% cases. Among these, 13.23% experienced highgrade fever (axillary temperature more than 104°F). However, these adverse events were self-limiting and did not require hospitalization. Fever was reported as a common complication (11,14). Additionally, Sharma et al, reported that fever occurred in over 80% of children following pentavalent vaccination (15). Most common systemic complication after vaccination was fever followed by restlessness (16).

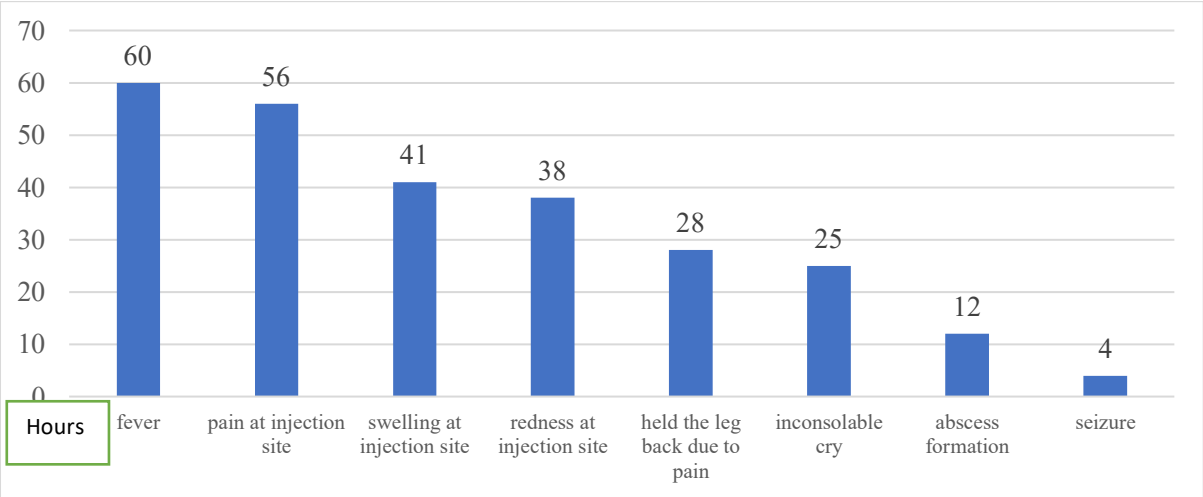

Figure 1. AEFI in Children After Pentavalent Vaccination

In the present study, other adverse reactions observed were pain at injection site (21.21%), swelling at injection site (15.53%) and redness at injection site (14.39%). Following pentavalent vaccination, 127 children (66.8%) experienced pain at the injection site, 84 (44.2%) developed swelling, and 72 (37.8%) showed redness at the injection site in a study conducted by Bansal et al (17). In a study by Khatereh et al (18), mild local reactions and pain were reported in 31.50% and 11.20% of cases, respectively.

Seizures were the least common AEFI reported in our study, occurring in 1.52% cases. Similarly, in a study by Khatereh et al. the least common AEFIs included encephalitis (0.1%) and convulsions (0.20%) (18). Seizure episodes caused by fever in 1.63 % of infants following pentavalent vaccine (19).

In the current study, the demographic profile and birth history of infants showed no effect on the adverse events following vaccination. Similarly, Karami et al. observed no significant difference in the incidence of complications following pentavalent vaccination between male and female children (20). In contrast, research by Dixit et al (11) reported that most AEFIs were reported in males (60.20%).

In the present study we did not find any serious adverse events such as death and any permanent damage. There was no evidence of encephalopathy post-pentavalent vaccination in our study. This finding aligns closely with study done by Paramkusham et al (21), which stated that there were only mild side effects such as local reactions at the injection site, fever, etc., with the highest frequency after pentavalent and BCG vaccines and no reports of serious effects, particularly permanent damage or chronic symptoms..

Fear of pain remains a common barrier to vaccination, although this was not observed among participants in our study. Concern about vaccine safety is a contributing factor to increased vaccine hesitancy, defined as delaying acceptance or refusing a vaccine despite its availability no fear of AEFI was found in our study group unlike the findings in the study done by Ma'rifati et al (22), which stated that fear of injections, vaccine hesitancy, AEFI concerns, perceived accessibility, and vaccine information - were found to be significantly associated with COVID-19 vaccine acceptance in Salatiga (p = 0.00 for each variable).

Research Limitations

The present study has the limitation of being a short-term study with small sample size. No major difficulty was faced while collecting the data. The first 24 hours after pentavalent vaccination are crucial to observe for any adverse events following immunization (AEFI). Within this time frame, the first six hours after immunization are particularly important. This finding can be used as a prognostic indicator for post-immunization counseling of parents at the clinic.

CONCLUSION

The findings of this study indicate that most adverse events following pentavalent vaccination were mild, non-serious, and resolved without the need for hospitalization. Serious complications, such as seizures, were rare and did not result in lasting harm. These results reinforce the safety of the pentavalent vaccine and support its continued use within the Universal Immunization Program. It is recommended that healthcare providers monitor infants closely in the initial hours following vaccination—particularly within the first six hours—and educate caregivers on expected reactions and warning signs. Further large-scale, multi-center studies are needed to strengthen the evidence base and guide policy on vaccine safety monitoring in India.

CONFLICT OF INTEREST

There are no conflict of interest.

AUTHOR CONTRIBUTIONS

All authors contributed significantly in this study. RS conceptualized the whole study and planned methodology. He also calculated statistics and had a significant role in writing this paper. BS did data collection, YS contributed in writing the original draft. RB mainly contributed in data collections, MK supervised the whole study.

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