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Original Research Article

A Mixed Cohort Study on Adverse Events Following Pentavalent Vaccine and Its Perception among Parents

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Abstract

Background and Objective: Vaccination stands as one of the most effective strategies for disease prevention and place and pivotal role in family and public health. Vaccines significantly reduce morbidity and mortality among children. However, despite its benefits vaccination can occasionally result in some adverse effects. Furthermore, while the vast majority of children experience no adverse effects to a vaccine, a small percentage may exhibit mild to severe side effects such as fever, redness and soreness of the injection site to convulsion and encephalopathy. Being informed about these potential outcomes empowers parents to make educated decisions about their child health care.

This study focuses to evaluate adverse effects post pentavalent vaccine, assess parental concern and determine continuation despite side effects.

Methods: This hospital based mixed cohort study was conducted from February 2021 to August 2022 enrolling 96 children who visited pediatric OPD for Pentavalent Vaccination. Data was collected in predesigned proforma and through the phone call after 48 hours of immunization.

Results: Most common adverse effect in first dose was fever (100%) and pain (100%) followed by redness (85.4%). Adverse effects in the subsequent doses were reduced. Only one participant (1%) had injection site abscess. There is significant association between the parents who are doubtful regarding vaccination and continuation of vaccination even after side effects (p-0.01).

Conclusion: Most of the children had minimal side effects. Incidence of adverse effects reduced in subsequent doses of vaccination. Most of the parents who were aware of adverse effects, and continued vaccination even after side effects.

Keyword: Adverse effects, Vaccination, Awareness.

Introduction

Immunisation has been a cornerstone in public health efforts to control and eradicate infectious diseases, Smallpox serves as a prime example of the profound impact vaccination can have, its global eradication stands as testament to the power and effectiveness of widespread vaccination campaigns. Additionally various other infectious diseases have been significantly reduced or eliminated regionally due to vaccination initiatives. Indeed, in terms public health interventions, vaccines offer a cost effective and efficient way to protect populations from potentially deadly diseases. [1]

World Health Organization (WHO), emphasizes the critical importance of vaccines in saving lives especially among children under the age of five. Current vaccines can prevent almost two million deaths in children under the age of five, each year. [2]The Expanded Program on Immunization (EPI), incorporates the Haemophilus influenza B (HIB) vaccine into the standard pediatric immunization schedule. HIB is responsible for causing meningitis and pneumonia, primarily affecting the children under the age of five. [3,4]

This burden of disease due to HIB is evident in both developed and developing nations.[5]. To enhance the effectiveness of vaccination particularly through the introduction of multivalent vaccines, new formulations have been incorporated into immunization program. In numerous countries the trivalent vaccine Diphtheria Pertussis Tetanus (DPT) has been substituted with the pentavalent (DTP-HepB-HIB) combination vaccines. [6] Implementing combination vaccines in pediatric

immunization schedules offers several advantages. These includes a reduction in clinical visits , decreased operational expenses for clinic, diminished pain through injections and heightened parental acceptance. However, concerns regarding vaccine safety have emerged due to reported incidence in various locations.[7] consequently, public hesitancy towards vaccines and perceived adverse effects can significantly impact the success of an immunization programme [8]

The potential side effects of the pentavalent vaccine can vary, ranging from mild to severe reactions. These adverse effects following the administration of the pentavalent vaccine encompass a spectrum that includes redness, and swelling at the injection site, fever, excessive Crying persisting for more than three hours, swelling at the site where the vaccine was administered, Seizures, and even Encephalopathy [9].

Such adverse reactions subsequent to immunisation can prompt parents to discontinue vaccination schedule for their children. Therefore the perceptions the parents hold regarding this particular vaccine, coupled with their awareness concerning the potential adverse effects linked to it , assumes a paramount importance. Addressing these concerns becomes essential to mitigate unnecessary anxiety among parents and to prevent any further discontinuation from the immunization programme.

Given the backdrop, the primary objective of the current study is to meticulously investigate this side effect associated with the primary doses of the pentavalent vaccines. Furthermore, the study seeks delve into how parents perceive these side effects and ascertain whether their amenable to continuing with subsequent immunization not withstanding any adverse occurrences that may have transpired previously.

Materials and Methods:

The present study was conducted at Tertiary health care centre, focussing on a mixed cohort of pediatric population aged between 6weeks to 14 weeks) from February 2021 to August 2022 . Before commencing the study, Ethical clearance and approval were obtained from the ethical and Research Committee of our institute.

Participants were selected based on the inclusion and the exclusion criteria.

Inclusion Criteria:

- All Children who attend Paediatric OPD for immunization between 6 weeks and 14 weeks of age.
- All parents willing to give informed consent

Exclusion criteria:

- Those who are not willing to participate in the study
- Those cases where follow up could not be done
- Preterm Neonates,
- Neonates with active infection

Study sample size: 96

The study utilized a printed questionnaire as its primary tool for data collection.

Additionally, online methods including emails and telephone calls were employed to gather information. A fully completed questionnaire served as the primary data source addressing adverse events related to pentavalent vaccination.

These events encompassed side effects such as fever, redness, swelling, excessive cry, convulsions and abscess at injection site. Post vaccination status updates were obtained via telephone within one or two days following vaccination.

The study focussed on children between 6 weeks to 14 weeks.

Results:

Of the participants, 96 (100.0%) reported experiencing Pain and fever after the first Dose. Additionally, 82 (85.4%) noted redness, 73 (76.0%) observed swelling, and 56 (58.3%) reported Excessive Crying following the initial dose.

Only 1 participant (1.0%) reported an injection Site abscess. (Table 1.)

Table 1: showing adverse effects after 1st dose of pentavalent vaccine

Adverse effect in 1st Dose	Yes	No
Pain	96(100.0%)	0(0.0%)
Fever	96(100.0%)	0(0.0%)
Redness	82(85.4%)	14(14.6%)
Swelling	73(76.0%)	23(24.0%)
Excessive Cry	56(58.3%)	40(41.7%)
Convulsion	0(0.0%)	96(100.0%)
Injection Site Abscess	1(1.0%)	95(99.0%)
Others	0(0.0%)	96(100.0%)

Following the second Dose, 92 participants (95.8%) reported experiencing pain while 4 participants (4.2%) did not experience any pain.

Regarding fever, 92 participants (95.8%) noted its presence, while 4 participants (4.2%) did not have any fever symptoms after second dose.

In terms of redness 30 participants (31.2%) observed it, whereas 66 participants (68.8%) did not experience any redness following second dose. Swelling was reported by 25 participants (26.0%), 71 participants (74.0%) did not experience any swelling. Similarly 25 (26.0%) reported excessive Crying, with 71 participants (74.0%) indicating no excessive crying after second Dose. 0 (0.0%) None of the participants, or 0 (0.0%) experienced convulsion or an injection site abscess following second dose. (Table 2.)

Table 2: showing adverse effects after 2ND dose of pentavalent vaccine

Parameters2nd Dose	Yes	No
Pain	82(85.4%)	14(14.6%)
Fever	92(95.8%)	4(4.2%)
Redness	30(31.2%)	66(68.8%)
Swelling	25(26.0%)	71(74.0%)
Excessive Cry	25(26.0%)	71(74.0%)
Convulsion	0(0.0%)	96(100.0%)
Injection Site Abscess	0(0.0%)	96(100.0%)
Others	0(0.0%)	96(100.0%)

After the third dose, 47 participants (49%) reported experiencing pain, while participants 49 (51%) did not. Regarding fever, 41 participants (42.7%) had it, whereas 55 participants (57.3%) did not. Redness of the local site of injection observed in 93 participants (96.9%), whereas only 3 participants (3.1%) did not experience it. Swelling of the injection site was reported by 95 (99.0%) with just 1 participant (1.0%) not having the swelling. Excessive cry was noted in 94 participants (97.9%), while 2 participants (2.1%) did not report this symptom. No participants reported convulsion or injection site abscess following the third dose.(table 3.)

Table 3: showing adverse effects after 3RD dose of pentavalent vaccine

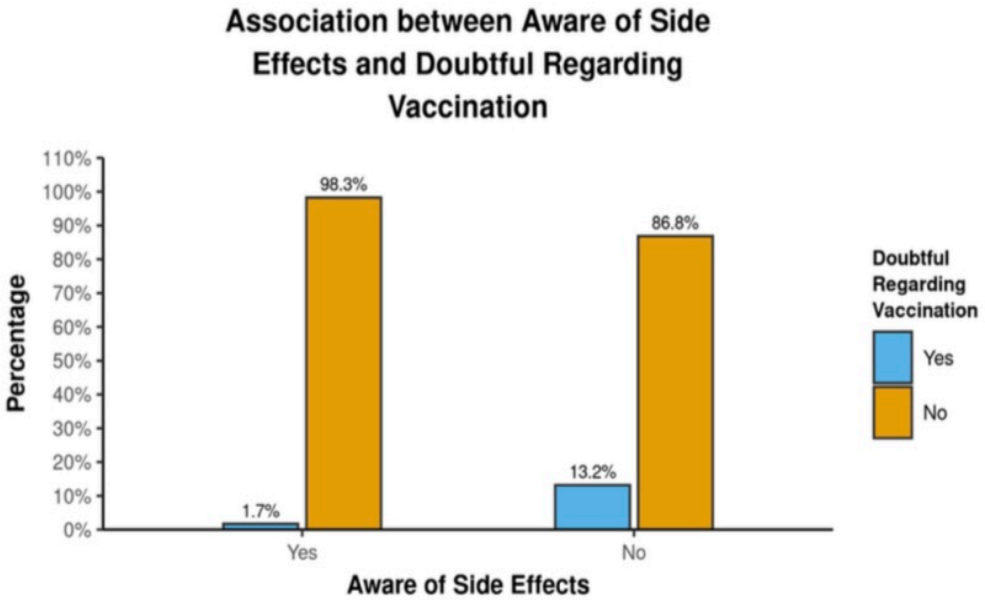
Parameters 3rd Dose	Yes	No
Pain	47(49.0%)	49(51.0%)
Fever	41(42.7%)	55(57.3%)
Redness	3(3.1%)	93(96.9%)
Swelling	1(1.0%)	95(99.0%)
Excessive Cry	2(2.1%)	94(97.9%)
Convulsion	0(0.0%)	96(100.0%)
Injection Site Abscess	0(0.0%)	96(100.0%)
Others	0(0.0%)	96(100.0%)

Of the participants 60.4% were aware of the side effects associated with the vaccination, while 39.6% were unaware. Regarding doubts about vaccination 6 participants (6.2%) expressed uncertainty, whereas significant majority 90 participants a (93.8%) harbored no doubts. Additionally 96.9% of the participants continued with the vaccination programme while 3.1% had discontinued it. (table 4.)

Table 4: showing parent's perception about awareness of pentavalent vaccine

Vaccine related details	Yes	No
Aware of side effects	58(60.4%)	38(39.6%)
Doubtful regarding vaccination	6(6.2%)	90(93.8%)
Continued vaccination program	93(96.9%)	3(3.1%)

In the group where participants were aware of the side effects, 1.7% expressed doubts about vaccination, while significant majority of 98.3 % did not have any doubts .Conversely, among those unaware of the side effects 13.2 % had doubts about vaccination while 86.8% did not harbor any doubts. The data indicates a significant association between awareness of side effects and doubts regarding Vaccination with a p- value of 0.034. (graph 1.)



Graph 1: Association between aware of side effcets and doubtful regarding vaccination

Discussion

This cohort study aimed to evaluate the incidence of adverse effects following the pentavalent vaccine administered to children at aged between 6, 10 and 14 weeks over 18 months. A total of 96 children were enrolled after obtaining informed consent from the parents. Pentavalent vaccines offer protection against five vaccine preventable diseases presenting advantages such as cost effectiveness, and convenience for both children parents. Although adverse events following immunization (AEFI) for individual components like DPT, Hep-B and HIB vaccines are well documented, comprehensive data for the combined pentavalent vaccines remain limited. [10]

The participants recognized the benefits of vaccination for child health, but often lacked detailed knowledge about potential adverse events and post vaccination care. Nevertheless, 93 participants (96.9%) continued the vaccination programme experiencing side effects. Various studies indicate that educational interventions have enhanced mothers understanding of adverse events related to the pentavalent vaccine. The objective of the present study was to assess the incidence of adverse events following pentavalent vaccination at 6,10 and 14 weeks and to find out the parents perspective regarding vaccination side effects and percentage of parents continuing vaccination after adverse events. After taking written informed consent, relevant data was collected using the preformed questionnaire through phone call after 24 hours of vaccination.

This hospital based mixed cohort study was conducted between February 2021 to August 2022, comprised 96 children attending the pediatric OPD for routine immunization.

Most frequent adverse effects observed after the initial dose were fever (100%) and pain (100%), followed by redness (85.4%). However, adverse effects diminished in subsequent second and third dose. None of them had any serious complication requiring hospitalization were reported. Only one participant (1%) had injection site abscess.

Findings revealed that 60% of parents were aware of potential side effects, while 40% of parents remain uninformed of side effects. Despite experiencing side effects a mere only 3% of the parents discontinued vaccination programme, indicating a high continuation rate of 97% even in the presence of side effects.

In conclusion adverse events following vaccination were minimal, and the majority of the parents remained committed to the vaccination schedule despite encountering side effects.

Conclusion

All the adverse effects observed were minimal, necessitating only basic interventions. Notably, the incidence of adverse effects was more prevalent following the first dose of pentavalent vaccine.

Subsequent doses of the pentavalent vaccine demonstrated a reduced incidence of adverse effects.

Majority of the parents exhibited awareness regarding the potential adverse effects associated with pentavalent vaccine and majority of the parents continued vaccination even after side effects.

A notable correlation was observed between the parent's awareness of side effects and their motivation to proceed with the vaccination.

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