RESEARCH ARTICLE

A Prospective Observational Study on Safety Evaluation of Immunization in Infants and Children

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Abstract

Objective: This prospective observational study aims to evaluate the safety of immunization in infants and children below one year of age.

Methods: In this study we have observed the immunity in children aged 0 to 12 months and followed the list of vaccinations given by the National Immunization Schedule. Data was collected from auxiliary nurse midwives or nurse hybrids (ANMs) and from the immunization book which is provided to parents. A cohort of 150 infants and children of age below one year are included in our study.

Results: The most common AEFI reported was fever, followed by swelling. Among the vaccines, the Pentavalent & oral polio vaccine (OPV) was majorly responsible for AEFIs, followed by measles and rubella (MR). Severe adverse reactions like Seizures are observed in 3 children for the pentavalent vaccine.

Conclusion: The present research study concludes that these AEFIs are common in children and they are not that harmful and the socio-economic parameters, lifestyle and food habits also affect immunization in infants and children.

Keywords: Immunization, Safety evaluation, ANMs, Infants, Lifestyle.

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INTRODUCTION

The pharmaceutical market gives fast-dissolving tablets (FDT) a unique place. Immunization plays a crucial role in preventing infectious diseases by stimulating the body's immune system to recognize and fight off specific pathogens, such as bacteria or viruses.[1] Vaccines introduce weakened or inactive forms of the pathogen or its toxins, allowing the immune system to develop memory cells that can recognize and quickly respond to the actual pathogen if encountered in the future.

This not only protects vaccinated individuals from becoming ill but also helps prevent the spread of disease within communities, contributing to herd immunity. Herd immunity occurs when a significant portion of the population is immunized, reducing the overall likelihood of disease transmission and protecting vulnerable individuals who cannot be vaccinated, such as newborns or those with compromised immune systems.[2] Immunization has been instrumental in eradicating or significantly reducing the incidence of many deadly diseases, such as smallpox and polio, and continues to be a cornerstone of public health efforts worldwide.[3]

Immunization in infants and children is vital for protecting them from a range of preventable diseases. Vaccination schedules typically begin soon after birth and continue throughout childhood, offering protection against illnesses such as measles, mumps, rubella, polio, diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenza type b (Hib), pneumococcal disease, rotavirus, and varicella (chickenpox), among others. These vaccines are administered at specific ages and intervals to ensure optimal immune response and protection.[1]

Immunization not only safeguards individual health but also contributes to community immunity, reducing the overall burden of infectious diseases and their associated complications in the population. Healthcare professionals recommend regular vaccination as a safe and effective way to protect children from serious illness and their potential long-term consequences.

Immunization

Immunization is the process where a person is made resistant to a disease, typically by the administration of a vaccine.

Active Immunization

Active immunization is the process of stimulating the body to produce antibodies and other immune responses through the administration of a vaccine or toxoid.

Passive Immunization

Passive immunization is the provision of temporary immunity by administration of preformed antibodies derived from humans or animals.[4]

Vaccine

The word vaccine comes from the cowpox virus vaccinia, which derives from the Latin word vacca for cow. The vaccine is an immuno-biological substance designed to produce specific protection against given diseases.

Types of Vaccines

Live attenuated vaccines

These vaccines contain a weakened form of the virus or bacteria that causes the disease, which stimulates an immune response without causing illness. Ex: BCG, OPV, MMR.

Inactivated vaccines

These vaccines contain killed versions of the virus or bacteria that cause the disease, which also stimulate an immune response. Ex: JE vaccine, Anti-rabies, Influenza killed vaccine.

Subunit, recombinant, and conjugate vaccines

These vaccines use specific parts of the virus or bacteria to stimulate an immune response rather than using the whole organism. Ex: Hepatitis B vaccine, human papillomavirus (HPV).

MRNA vaccines

These vaccines use a small piece of genetic material called messenger RNA to instruct cells in the body to produce a protein that triggers an immune response. Ex: Moderna COVID-19 vaccine.

DNA vaccines

These vaccines use a small piece of DNA that contains genetic instructions for making a protein that triggers an immune response. There are currently no DNA vaccines approved for use in humans, but research is ongoing in this area.

Viral vector vaccines:

These vaccines use a harmless virus as a delivery system to introduce genetic material from the virus or bacteria that causes the disease into cells, triggering an immune response. Ex: Johnson & Johnson COVID-19 vaccine.

Toxoid vaccines

These vaccines use a toxin produced by the bacteria that causes the disease, which has been chemically altered to make it harmless but still capable of stimulating an immune response. Ex: Tetanus toxoid vaccine and Diphtheria toxoid vaccine.

Recombinant vector vaccines

These vaccines use a genetically engineered virus or bacterium to deliver genetic material from the virus or bacteria that causes the disease into cells, triggering an immune response. Ex: Ebola virus vaccine (Ervebo).[5]

Immunization is a critical public health intervention that has significantly reduced the burden of infectious diseases Worldwide. However, concerns about the safety of vaccines continue to be a topic of debate among parents and healthcare providers. In order to address these concerns and provide evidence-based recommendations, it is essential to conduct rigorous observational studies to evaluate the safety of immunizations in infants.[6,7] Table 1 enlists about national immunization schedule for infants and children of 1-year of age.

Table 1: National immunization schedule for infants and children of 1 year of age

Vaccine	*When to given*	*Dose*	*Route*	*Site*
BCG	At birth or as early as possible 1 year of age	0.1ml (0.05ml unit 1 month of age)	Intradermal	Left Upper Arm
Hepatitis B-Birth dose	At birth or as early as possible within 24 hours	0.5ml	Intramuscular	Anterdateral side of midthigh
OPV-0	At birth or as early as possible with in the first 15 days	2 drops	Oral	Oral
OPV-1,2&3	At6weeks,10 weeks & 14 Weeks (OPV can be given till 5 years of age)	2 drops	Oral	Oral
Pentavalent 1,2&3	At 6 Weeks,10 weeks & 14 weeks (can be given till one year of age)	0.5ml	Intramuscular	Anterdateral side of midthigh
Rota virus	At 6 Weeks , 10 Weeks & 14 Weeks (can be given till one year of age)	5 drops	Oral	Oral
IPV	Two fractional dose at 6 and 14 Weeks of age	0.1 ml	Intradermal two fractional dose	Intradermal Right upper arm
Measles/ MR1st Dose	9 Completed months (can be given till 5 years of age)	0.5ml	Subcutaneous	Right Upper arm
JE-1	9 completed months	0.5ml	Subcutaneous	Left upper arm
Vitamin A (1st dose)	At 9 completed months with measles and rubella)	1ml	Oral	Oral

Methodology

Accurate immunization data is necessary to assess vaccine coverage, safety and effectiveness. We have collected the immunization data of the children aged 0 to 12 months and the comparison between the partial and total percentage of vaccination in the children of 0 to 12 months age as per National immunization schedule estimates about the proportion of children fully vaccinated. We have also collected information from ANMs to estimate the vaccine coverage.

Study site: Venkateswara Mother and Children Hospital
Study type: Prospective observational study
Study period: 4 months
Sample size: 150 cases

Inclusion Criteria

- Infants and children aged 0 to 12 months are scheduled to receive routine vaccinations at participating healthcare facilities.
- The study population may be either male or female.
- List of vaccines that are given to infants as per the National Immunization Schedule.

Exclusion Criteria

- People and children who are above 1-year of age are excluded.
- Pregnant women are also excluded.
- People who are uninterested to participate in the study are also excluded.[8]

Results and Discussion

The data for gender-wise distribution was summarized in Table 2. Of 150 numbers of infants and children, 76 numbers are male, and 74 are female. The same is presented in Figure 1.

Age-wise distribution is based on the vaccines which are given frequently to infants and children at 6, 10, &14 weeks of age. Data was presented in Table 3 and Figure 2.

Any vaccine can have adverse reactions but they are not that harmful. They can be treated. Data for intensity of adverse reactions was presented in Table 4.

Table 2: Gender-wise distribution

Gender	*Number*
Males	76
Females	74

Table 3: Age-wise distribution

Age-wise distribution based on vaccine administration	*Distribution in number*
0–1 month	47
1–2 months	23
2–6 months	44
6–12 months	36

From the entire group, the parents of one child refused the vaccination with the BCG vaccine at birth because the baby was born underweight and incubated. The most severe side effects were counted for the pentavalent vaccine (three refusals of the initial dose at 2 months and two refusals at 3 months). Parents of some children consulted social media in order to be informed about vaccines. From this group of parents, some of them refused the vaccination and the rate varies with the type of vaccine (the highest rate being observed in the case of the pentavalent vaccine).

The adverse reactions induced by vaccinations were followed during the first year of life and the reactions after the mandatory vaccines included in the national program of vaccination were counted.

The present observational study demonstrated that vaccines are a safe preventive method for infectious diseases in children below 1 year old. Vaccines represent one of the most important preventive strategies in pediatric populations. In the last decade, the concerns regarding vaccine safety have risen significantly and, in particular, parents are continuously questioning the need for and the safety of vaccines. Therefore, the vaccination rates have fallen to a suboptimal level in some countries and communities.

In this study, 150 members of infants and children are

Table 4: Intensity of adverse reactions of vaccines

Vaccines	*Intensity of adverse reactions*				
	No AD	*Mild*	*Moderate*	*Severe*	*Refusal*
BCG	115	23	11	0	1
Hepatitis-B	143	5	2	0	0
OPV	95	34	21	0	0
Pentavalent	113	20	9	3	5
Rotavirus	130	15	5	0	0
IPV	125	17	8	0	0
MR 1st Dose	91	37	20	2	0
JE-1st Dose	100	28	19	0	0
Vitamin-A	140	7	3	0	0

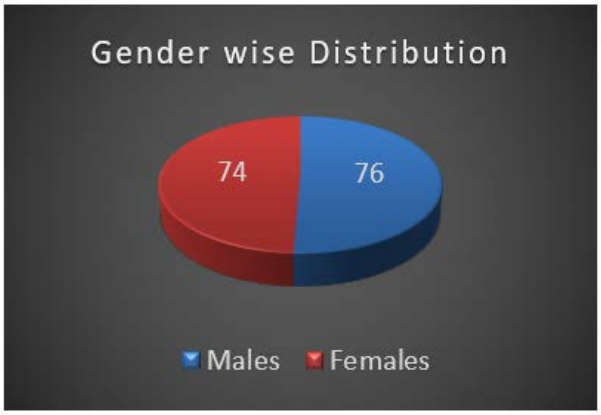

Figure 1: Gender-wise distribution chart

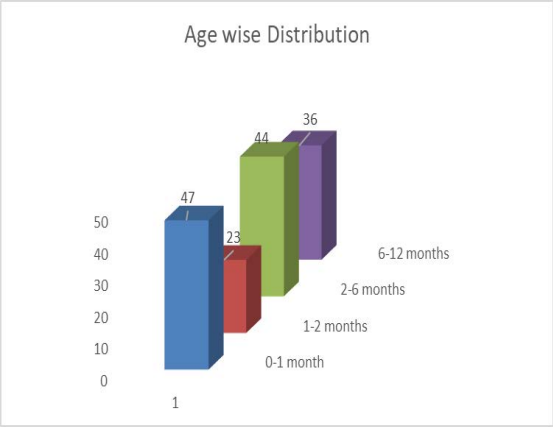

Figure 2: Age-wise distribution chart

included, in 76 are males and 74 are females and 129 were vaginally delivered and 21 were caesarian delivered. In them, few of their parents completed their primary level of education and they were aware of immunization & its importance. So they completed the process of vaccination for their children within time successfully. The remaining parents were not educated, so they hesitated at first for fear of side effects and delayed the vaccination process for their children. We found that for all vaccinations, there were mild and moderate adverse reactions like fever, swelling at the injection site and rashes observed and they were treated. For pentavalent vaccination and MR ^{1st} dose, severe adverse reactions like febrile Seizures were observed and for treatment, they had to counsel the specialist immunization clinic or neurologist.

Conclusion

In conclusion, the prospective observational study on the safety evaluation of immunization in infants and children below 1 year of age represents a significant contribution to the field of pediatric vaccination. In our study, we conclude that Vaccines administered to children below 1 year are safe and continuous monitoring of labeling of vaccine vials is necessary to avoid complications. If the color of the label of vaccine vials gets changed, then they should be discarded, as they are exposed to the outer environment and they should not be used to avoid further complications. We conclude that these AEFIs are common in children and they are not that harmful, and the socio-economic parameters, lifestyle and food habits also affect immunization in infants and children.

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References

1. Arora NK, Das MK, Poluru R, Kashyap NK, Mathew T, Mathai J, Aggarwal MK, Haldar P, Verstraeten T, Zuber PL. A prospective cohort study on the safety of infant pentavalent (DTwP-HBV-Hib) and oral polio vaccines in two South Indian districts. The Pediatric Infectious Disease Journal. 2020;39(5):389-396.
2. Sabin AB. Immunization: Evaluation of some currently available and prospective vaccines. Journal of the American Medical Association. 1981;246(3):236-241.
3. Pop CF, Coblisan P, Capalna L, Panţa PC, Buzoianu AD, Bocsan IC. Safety of Vaccination within First Year of Life–The Experience of One General Medicine Center. Children. 2023;10(1):104.
4. McDonnell WM, Askari FK. Immunization. Journal of the American Medical Association. 1997;278(22):2000-2007.
5. Kallerup RS, Foged C. Classification of vaccines. InSubunit vaccine delivery. New York, NY: Springer New York, 2014 :15-29.
6. Ramteke Rachana, Tawalare Kalpana, Sharma Mrityunjay, Tawalare Kiran, Sharma Harshala. Evaluation of effect of shaktivardhak yog in upper respiratory tract infections. International Journal of Ayurveda and Pharma Research.2014;2(4):99-102.
7. Sears RW. The vaccine book: Making the right decision for your child. Little, Brown Spark; 2011:126.
8. R. Saravanan, Farahan Subhahan. Safety Evaluation of Vaccines in Pregnant women and Infants. Journal of Pharmaceutical Negative Results. 2022;13(10):4987-4997.

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