



Prophylactic Use of Paracetamol on Routine Vaccination Induced Fever and Febrile Convulsion

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ABSTRACT

Vaccination is one of the great accomplishments in the field of public health. Routine vaccination is extremely beneficial for children. But the reasons for noncompliance are the adverse effect of the previous immunization. A total of 1348 children belonging to the age group 0-6 years were studied for a period of six months for assessing the efficacy of paracetamol prophylaxis for fever and convulsion in routine immunization practice. Prophylaxis was done in half of the children. The children's were observed by parents for a period of 48hours after immunization. Paracetamol in the dose of 15mg/kg/dose was given in half of the children for 48hours, 6-8 hourly starting 0-30 minutes before the immunization. There was about 50% reduction in the occurrence of fever and with no convulsion in the prophylactic group. The use of prophylactic paracetamol may be reconsidered for reduction in post vaccination adverse effect of which fever and convulsion are major sequelae. This strategy may reduce the noncompliant parents and the immunization drop out cases.

KEYWORDS : vaccination, fever, convulsion, paracetamol

INTRODUCTION

Immunization is one of the great accomplishments of the field of public health and routine vaccination is extremely beneficial for children.[1] But the main cause for drop out and noncompliance is the post vaccination adverse effects which may be in the form of local and systemic. Among the systemic effects, fever and convulsion are most important.

Since febrile reaction and febrile convulsion play a major role in the parent perception of vaccine tolerability and might even stop parents from having their infant immunized, there is a tendency to use prophylactic paracetamol (Acetaminophen) as a part of immunization practice.[2] Studies on prevention strategy is scarce. Therefore to assess this approach we performed a study on prophylactic oral administration of paracetamol in routine immunization practice, which includes OPV, DPT, Hepatitis-B, Measles and MMR. The study was performed with following objectives :

1. To compare the occurrence of fever and febrile convulsion in two groups :-

i.Group-I (P) - Receiving paracetamol 0-30 minutes, prior to immunization.

ii.Group-II (C) - Prophylactic paracetamol was not given except in the situation when post vaccination relevant symptoms demanded the use of paracetamol.

2. To analyze, whether the observation helps in counseling of the parents where study results can be used in routine immunization practice regarding post vaccination febrile episode and or, convulsion.

PATIENT AND METHOD

The study was conducted in 1348 children in immunization clinic belonging to 0-6 years of age within a period of six months from 01.04.15 to 30.09.15, attending Tripura Medical College and Dr. BRAM Teaching Hospital. The recruited subjects were divided in two groups.

Group-I (P) : received prophylactic paracetamol at the time of immunization (0-30 minutes before).

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Group-II (C) : was not given paracetamol except in situation where its use was demanded by post vaccination clinical condition.

Paracetamol was given 0-30 minutes prior to vaccination in the dose of 15mg/kg/dose 6-8hourly for a period of 24-48 hours.

Only healthy children's were included in the study group. Criteria considered for exclusion in the study included :

1. Gestational age <37 weeks and /or birth weight <2500 gms.
2. Failure to thrive.
3. Immune deficiency / suppression.
4. Severe congenital malformations.
5. Neurological or other severe chronic disorder.
6. Any history of seizure.
7. Bleeding disorder, prior administration of blood product, antipyretics for other indication, intolerance to paracetamol, etc.

Fever was graded as:-

- Mild – 38-38.9°C
- High – 39-40.4°C
- Extreme ≥40.5°C

Fever was measured in axilla. One endogenous elevation of temperature in 24 hours was considered fever i.e. ≥38°C. Parents were asked to note the fever six hourly for 48hours and advised to report after two days at immunization clinic.

RESULTS

Out of 1348 vaccinated children, 670 children received paracetamol and the rest 678 of them did not. The participants in present study included 54.6% male and 45.4% female children.

TABLE-I : Distribution of subjects in designated groups.

| Group | Total no. | Gender distribution | |
|--------------|-----------|---------------------|-------------|
| | | Male | Female |
| Group-I (P) | 670 | 368(54.92%) | 302(45.07%) |
| Group-II (C) | 678 | 368(54.27%) | 310(45.72%) |
| Total | 1348 | 736(54.6%) | 612(45.4%) |

Mild fever of 38°C to 38.9°C within 48hours was seen in 22.53% children in group-I (P), where as 51.03% children had fever in group-II (C). High fever of 39°C TO 40.4°C was observed in 3.13% children in group-I (P) and 11.79% in group-II (C). No children in group-I (P) had convulsion, where as in group-II (C) 4(0.59%) children developed febrile convulsion.

TABLE-II : Distribution of subjects developing fever in designated groups.

| Group | Fever of Temperature range [n(%)] | | |
|---------------------|-----------------------------------|------------|---------|
| | 38-38.9°C | 39-40.4°C | >40.4°C |
| Group-I (P) [n=670] | 151(22.53%) | 21(3.13%) | 0 |
| Group-II(C) [n=678] | 346(51.03%) | 80(11.79%) | 0 |

DISCUSSION

Extreme category fever was not observed in the present study i.e. ≥ 40.5°C. Mild fever was observed in group-I(P) 151/170 (22.53%). In group-II(C) it was seen in 346/678 (51.03%). Fever of high grade was observed in group-I(P) 21/670 (3.13%) and in group-II(C) 80/678 (11.79%). Fever may be present upto 10% of vaccination except DPT, where fever may be present in half (50%) of the cases.[3] In this study mild fever in group-II (C) was present in 51.03% cases. Incidence was less than half in group-I (P) i.e. (22.53%). So in the present study the incidence of fever was present in less than half of group-II(C) in the Paracetamol used category. In the mild fever category, according to a recent study, incidence of fever in Paracetamol versus Control group was stated as 26.6% versus 43.5%.[4] In the present study, Paracetamol versus Control group was observed to be 22.05% versus 51.03%. In the same study, high fever was observed in 3.3% in group-I(P) and 12.7% in group-II(C) which is similar to our observation, stating as 3.13% versus 11.79%. Park et al states that post vaccination convulsion is mainly due to pertussis, measles and MMR and is less than 1%.[3] The present study is consistent with this statement, observation being 0 versus 4 (0.58%) in Paracetamol versus Control group. The present study clearly indicates that prophylactic paracetamol significantly lower the incidence of fever (mild and high) and convulsion. This finding is consistent with observations reported by other authors. [1,2,5]

There is controversy in using paracetamol to reduce post vaccination symptom, because there are reports that this approach may cause lowering of the antibody titre [6,7]. On the contrary it is also said that the antibody response is not lowered below sero-protective level. So it is unlikely that prophylactic paracetamol would have any detrimental effect on individual child concern[4]. According to a study reported from Czech republic, more than 96% of children achieved antibody titre considered protective whether or not they have received prophylactic paracetamol.[5] A recent study showed a high proportion of participants still achieved immune responses to co-relate with protection, suggesting that vaccine efficacy was not impaired.[8]

CONCLUSION

Prophylactic paracetamol use in vaccination may be reconsidered because occurrence of a single high fever and or convulsion usually prevents the community participation, especially in developing countries where adequate literacy and awareness lacks. This acts as a stigma and results in poor or delayed attendance in immunization clinic. As prophylactic paracetamol use does not lower the Antibody titre below protective level and side effects of paracetamol in pharmacological dose being negligible, transient use of paracetamol may remove the inhibition and improve the attendance in immunization clinic. It is a proven fact that vaccination is the only cost effective disease preventing system.

REFERENCES

- Humera Hayat, Parwez Sajad Khan, Gazala Hayat. The effect of prophylactic paracetamol administration on adverse reaction following DTP vaccination. Eastern Journal of Medicine,2011;16:258-260.
- Markus A Rose,Christine Juergens,Beate Schmoele-Thoma et al. An open level randomized clinical trial of prophylactic paracetamol administered with seven valent pneumococcal conjugate vaccine and hexavalent diphtheria toxoid, tetanus toxoid, 3-component acellular pertussis, hepatitis B, inactivated polio virus and haemophyllus influenza type B vaccination. BMC Pediatrics, 2013; 13:98.
- Park K. Park Textbook of prevention and social medicine. Adverse events following immunization, 23rdEd, M/S Banarasi Das Bhanot, 1167 Prem Nagar, Jabalpur, 482001 (MP), INDIA.
- Rashmi Ranjan Das, Inusha Panigrahi, Sushree Samiksha Naik. The effect of prophylactic Antipyretic administration on post vaccination adverse reaction and antibody response in children : A systematic Review. PLoS ONE,2014; 9(9): e106629.
- Jason MH, Philip RF. Prophylactic Paracetamol at the time of infant vaccination reduces the risk of fever but also reduces antibody response. Evidence based medicine, 2010; 15:50-51.
- Roman Prymula, Claire-Anne Siegrist, Roman Chlibek et al. Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-label, randomised controlled trials. Lancet 2009; 374: 1339-50.
- Doedée AMCM, Boland GJ, Pennings JLA, et al. Effects of Prophylactic and Therapeutic Paracetamol Treatment during Vaccination on Hepatitis B Antibody Levels in Adults: Two Open-Label, Randomized Controlled Trials. Gluud LL, ed. PLoS ONE. 2014;9(6):e98175.
- Burlacu Alexandru. Prophylactic Paracetamol lowers the effect of childhood vaccine. MAEDICA- Journal of Clinical Medicine,2009; 4(4):362.