

In the name of God



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Survey of Complications of Triple Vaccine in Yazd in 2005.

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Abstract:

Background: Simultaneous immunization against diphtheria, tetanus and pertussis during infancy and childhood has been a routine practice in Iran. According to WHO protocol, report of adverse reactions of vaccination as side-effects to collect information and incidence of them must be done.

Objective: to determine the complications of triple vaccine in referrals of the health centers of Yazd in 2005.

Methods: This cross sectional and descriptive study was carried out on all of 474 cases with DPT vaccination. The probably complications during 72h followed and observed symptoms were collected in questionnaire and the data were analyzed statically.

Results: In 474 vaccinated children, complications had been seen in 81.430% (n=386). they were 185 (80.79%) boys and 201 (82.04%) girls. the most children were who received 1st time and 1st repetitive time. most prevalent complications were fever(56.8%), pain in the injection area (55%), swelling (26.8%), crying (11.4%), loss of appetite (11.2%), non-humorous behavior (11%), erythema (10.5%), and vomiting (6.5%). the other side effects were: persistant crying, injection site erythma, vomiting and lethargy.

Conclusion: complications after triple vaccination were rather high in Yazd. So it is recommended to recognize the causative factors and its reduction.

Keywords: Vaccine, Diphtheria, Pertussis, Tetanus, Complication, Triple.

Introduction:

Though considerable success in prevention and control of infectious disease because of so threaten of them, Prevention especially in vaccination method is still important and even only effective way to reduce infection disease.^(1, 2)

Besid of vaccination benefits, some adverse effects especially in DTP (diphtheria, tetanus and pertusis) vaccine worry parents and physicians.^(3, 4) some of these unwanted effects in DTP vaccination are: topical reactions like pain and swelling of injection site and systemic reactions like fever, narcosis, loss of appetite, vomiting and persistent cry usually without disrupt of immunization process.⁽⁵⁾ But some complications like epilepsy, encephalopathy or high temperature cut of vaccination in next times.⁽⁶⁾

Variety and severity of DTP vaccine complication has been reported different by multi studies like Cody, Marcinak and Taghavi.

Patients and Methods:

To do a descriptive and cross sectional study to investigate the complications of triple vaccine in referrals of the health centers of Yazd in 2005, according to previous studies with confidence level ($1-\alpha$) = 95% and delicacy level (d) = 0.05 we must enroll at least 387 cases to investigate. In our study ,We entered all of 474 children lesser than 6 years old (from 1.5 month to 6 years old) who referred to all health centers of Yazd city to do triple vaccination according to country program.

They could be in different appointment of vaccination (first, second or third time or repetitive time). In all of children we filled provided questioners with demographic information and then the DPT vaccine according to country program (0.5 ml IM) injected. In first and third day after injection, in call, we asked the parents about the probably reactions related to DPT vaccine. Data were collected and then we used SPSS 11.5 software (SPSS Inc., Chicago, IL, USA) to analyze statically.

Results:

Among 474 children lesser than 6 years old under going DPT vaccination, 229 (48.3%) were boys and reminders ($n= 245$, 51.6%) were girls. this study included 111 (23.42%) children in 1st time, 93 (19.62%) in 2nd time, 77 (16.24%) in 3rd time, 78 (16.45%) and 115 (26.26%) in 1st and 2nd repetitive time of triple vaccination (figure1). in 474 vaccinated children, complications had been seen in 81.43% ($n=386$). they were 185 (80.79%) boys and 201 (82.04%) girls.

Fever (56.8%), pain (55%) and swelling (26.8%) were the most frequent reported complications (table 1) (some children had more than one complication). In 386 complicated children, 84.6% ($n=94$) were in 1st time, 77.3% (89) in 2nd repetitive time, 81.7% ($n=76$) in 2nd time, 84.6% ($n=66$) in 1st repetitive time and 79.2% ($n=61$) in 3rd time respectively. From 88 uncomplicated children, the most children were who received 2nd repetitive time vaccine ($n=26$ 22.6%) (Table 2)

Table 1, Frequency of complications according to sex.

Sex	Fever	Pain	Swelling	Persistent cry	Loss of appetite	Malaise	Redness	Vomiting	No complication
Boy N=229	148 (64.6)	139 (60.7)	71 (31)	26 (11.4)	26 (11.4)	33 (14.4)	18 (7.9)	15 (6.6)	44 (19.2)
Girl N=245	121 (49.3)	122 (49.7)	56 (22.9)	28 (11.4)	27 (11)	19 (7.8)	32 (13)	16 (6.5)	44 (18)
Add N=474	269 (56.8)	261(55)	127 (26.8)	54 (11.4)	53 (11.2)	52 (11)	50 (10.5)	31 (6.5)	88 (18.9)

Table 2, Frequency of vaccinated children at complication accrues and vaccination appointment.

Time	Presence	Absence	Total
First	(84.6)94	(16.5)17	(100)111
Second	(81.7)76	(18.2)17	(100)93
Third	(79.2)61	(20.7)16	(100)77
1st repetitive	(84.6)66	(15.3)12	(100)78
2nd repetitive	(77.3)89	(22.6)26	(100)115
Total	(81.43)386	(18.57)88	(100)474

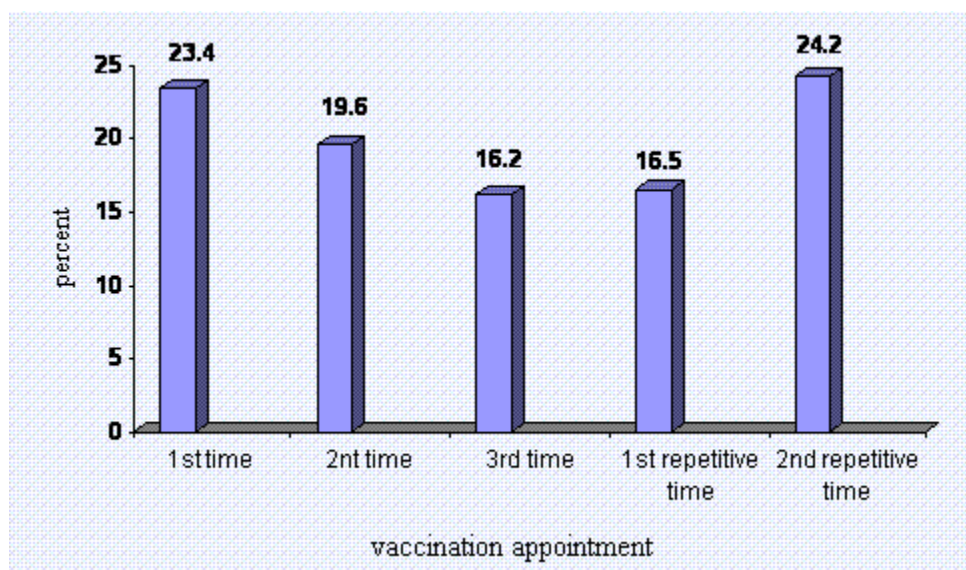


Figure 1, distribution of children according to vaccination appointment.

Discussion:

Adverse reactions associated with administration of DPT immunizations in infants and children could be present. DPT combination is diphtheria-pertussis and tetanus toxoids.⁽⁶⁾ 81.43 % (n=386) of our studied children had complications that is lesser than of 89.8% by similar study of Taghavi I in Kashan.⁽⁷⁾ The frequent complications in our study were: fever, pain and swelling of injection site respectively. In Kashan study, how ever malaise was instead of swelling in our study but fever and pain also reported as the most common complications. In comparison of results of study by Cody (pain; 44.6%, swelling; 31.3% and erythema; 27.7%)⁽⁸⁾ Pain and swelling in our study is higher and erythema is decreased. In our study also erythema (10.5%), persistent cry (11.4%), loss of appetite (11.2%), malaise (11%) and vomiting (6.5%) evaluated that was similar items with variable outcomes from Kashan study. Variations of study results can depend on describe of complication, injection practice and type of vaccine for example in Yazd and Kashan study temperature higher than normal range considered as fever but in Cody study fever supposed temperature above 38.3. The high presentation of fever inducing by DPT immunization (63%) has been reported in a study by Marcinak in 1993.⁽⁹⁾ Ferry in 1982 reported fever and restless as the most frequent adverse effects.⁽¹⁰⁾ They reported lack of stimulus responses in 1% of children that hasn't been seen in Kashan and our study. With attention to date of Ferry study

(20 years ago), different vaccine qualities pose as probable cause. Sex predominance has been seen in complications of fever, swelling, malaise and loss of appetite in our study (male > female) (table 1) but in Kashan study, it was equally without no specific reason., in five levels of plan (According to country immunization schedule for preschool children) no correlation between stage and frequency of complications found in Yazd and Kashan study, but in study of Flavo in 1994, complications increased depending on higher level of immunization.⁽¹¹⁾ It maybe results of different constitutional reactions to vaccine, type of vaccine or practice injection. Some studies like Edwards KM^(12, 13) and Greco D⁽¹⁴⁾ also suggest the correlation of more adverse reactions more in subjects with higher average age (probably because of Pertusis). To prevention of adverse reactions following triple vaccination of infants, Acetaminophen prophylaxis administration has been pointed by IPP MM and Lewis K in separated studies^(15, 16)

Conclusion:

In conclusion, high average age and Pertusis particle of triple vaccine have main role to induce adverse reactions. So it suggested replacing of DPT vaccine with DPaT vaccine and administration of acetaminophen before injection to reduce complications. We suggest also continuous studies to evaluate adverse reactions of routine vaccination and preventing programs to reduce them.

References:

1. Bartlett JG. Update in infectious diseases. *Ann Intern Med* 2000; 133: 285.
2. Weiss RA. Virulence and pathogenesis. *Trends Microbiol* 2002; 10: 314.
3. Offit PA, Quarles J, Gerber MA. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics* 2002; 109: 124-129.
4. Offit PA, Hackett CS. Addressing parent's concerns: Do vaccines cause allergic or autoimmune diseases? *Pediatrics*. 2003; 111: 653-659.
5. Chen RT, Davis RL, Sheedy KM. Safety of Immunizations. In: Plotkin SA, Orenstein WA, eds. *Vaccines*. 4th ed. Philadelphia, WB Saunders; 2004; 1557-1581.
6. Orenstein WA, Wharton M, Bart KJ. Immunization. In: Mandel GL, Douglas RG, Bennet JE, editors. *Principles and Practice of Infectious Diseases*. Edinburgh: Churchill Livingstone. 2005; 3557-3585.
7. Taghavi Ardakani Abbas, Talebian Ahmad. complications of triple vaccine in Kashan in year 2000. *Feiz journal*. 2002; 17: 33-37
8. Cody CL, Baraff LY, Cherry JD. Nature and rates of adverse reactions associated with DTP and DT immunization infants and children. *Pediatrics*. 1981; 68: 650-660.
9. Marcinak JF, Ward M, Frank A. Comparison of the safety and immunogenicity of acellular and whole cell pertussis vaccine. *Am J Dis Child*. 1993; 147: 290-294.
10. Feery BJ. Incidence and type of reactions to triple antigen (DPT) and DT vaccines. *Med J Aust*. 1982; 2: 511-515.
11. Flavo C, Horowitz H. Adverse reactions associated with simultaneous administration of multiple vaccines to travelers *J Gen Intern Med*. 1994; 9: 255-260.
12. Edwards KM, Decker MD. Challenges for licensure of new diphtheria, tetanus toxoid, acellular pertussis (DTaP) combination vaccines: counterpoint. *Pediatr Infect Dis J* 1996; 15: 1070-1073.
13. Edwards KM, Decker MD. Combination vaccines consisting of acellular pertussis vaccines. *Pediatr Infect Dis J* 1997; 16(suppl 4): S97-S102.
14. Greco D, Salmaso S, Mastrantonio P. A controlled trial of two acellular vaccine and one whole-cell vaccine against pertussis. *N Engl J Med* 1996; 341-348.
15. IPP MM, Gold R, Greenberg S. Acetaminophen prophylaxis of adverse reactions following vaccination of infants with diphtheria-pertussis-tetanus toxoids-polio vaccine. *Pediatr Infect Dis J* 1987; 6: 721-5.
16. Lewis K, Cherry JD, Sachs MH, et al. The effect of prophylactic acetaminophen administration on reactions to DTP vaccination. *Am J Dis Child* 1998; 142: 62-5.