The Comparison of the adverse events of Pentavalent and DPT vaccines in 2-6 months infants in Iran: A national study

Ghobad Moradi

Kurdistan University of Medical Sciences

Zaher Khazaei

Kurdistan University of Medical Sciences

Seyed Mohsen Zahraei

ministry of health and medical education, tehran

Fateme Yaghini

ministry of health and medical education, tehran

Mohiadin Amjadian

Kurdistan University of Medical Sciences

Daem Roshani (✉ daemroshani@gmail.com)

Kurdistan University of Medical Sciences <https://orcid.org/0000-0003-4746-1114>

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Abstract

Background Vaccination is the most remarkable intervention in public health and is an effective strategy in order to control infectious diseases among infants. This study attempted to compare the adverse events of Pentavalent and DPT vaccines together. **Methods** This is a cross sectional (analytical-descriptive) study in which the 2-6 months healthy infants, having received DPT in 2013 and Pentavalent in 2015, were studied for their experienced adverse events related to these vaccines. Percentage, mean, standard deviation and chi-square tests were used to describe and analyze the data. **Results** The results showed that 10464 and 17561 adverse events, which are associated with DPT and Pentavalent respectively, were recorded in the infants who received these vaccines throughout Iran. Mazandaran, Qazvin and Golestan provinces reported the highest number of adverse events, respectively (15.74%, 11.25%, and 9.12%). Moreover, Pentavalent seemed to have more recorded adverse events compared to DPT, high fever had the highest record rate for DPT (47.4%) and mild localized complications was the highest for Pentavalent (31.68%). There was a significant relationship between the kind of vaccine and the type of reaction, adverse event categorization, the country produced the vaccine and the infants' place of residence ($p < 0.05$). **Conclusion** Severe localized adverse events including high fever, vomiting, diarrhea and restlessness seemed to be less in Pentavalent compared to DPT vaccine. Therefore, substituting Pentavalent for DPT in infants seems to reduce the adverse events among them.

Background

World Health Organization (WHO) considers vaccination in infants as the most influential health intervention for promoting the society health in the world(1) . Infants' vaccination program has been merged into public health service networks from their starting point in Iran and having 98% of infants vaccinated, it has brought a great success in eradicating, removing and controlling preventable diseases(2-4). Although modern and new vaccines used throughout the country are supposed to be safe, there is no vaccine without adverse effects. Each vaccine has got its own side-effects which might appear following their use(5). Based on the World Health Organization and Iran's care guide recommendations, regardless of any causal relationship, every side-effect observed in the vaccinated person who is assigned to the vaccination procedure by physicians, family members or the person himself is known as an adverse event following immunization(6). Immunization adverse events can be due to errors in vaccination program, reactions due to the nature of the vaccine, reactions to injection or unknown factors. Sometimes there might be some adverse events temporarily assigned to vaccination because of their concurrency(5, 7).

Furthermore, Pentavalent immunization program, used to prevent hepatitis B, Diphtheria, anthrax, Tetanus and Haemophilus influenzae type b (Hib) flu and injected in three different time intervals(2,4 and 6 months), started in October 2014 in Iran(8). This vaccine is used broadly in more than 100 countries for preventing DPT (Diphtheria, Tetanus, and Pertussis), Hepatitis B and Hib in recent years. A study in the USA showed that fever (25.8%), injection site sensitivity (15.8%) and injection site edema (10.8%) were the most remarkable adverse events of Pentavalent vaccine(9, 10) . Some of the Pentavalent vaccine

advantages includes reducing the number of injections and syringe usages, less pain and restlessness in infants, decreasing the complications of injection, ease of planning, cost of its effectiveness and increasing the immunization coverage(11).

However, no national study has been done on the possible adverse events of this vaccine in Iran since its merging into the country's national vaccination program in November 22nd2014(10). This study attempted to broadly compare the possible adverse events of Pentavalent as a new vaccine in comparison to DPT vaccine in infants of 2-6 months in Iran in 2016.

Methods

This is a cross sectional (analytical-descriptive) study. All healthy infants (male and female of 2-6 months), who visited health centers to receive DPT from the 18th of April to the 25th of March in 2013 as well as those who received Pentavalent from April 30 to March 25, 2015 and having experienced adverse events following vaccination were studied. Those infants with allergic reactions or convulsions prior to vaccines and those who received immunosuppressive and neurological disorder medications were excluded from the study. Pentavalent and DPT vaccines used in this study had been produced in Iran, Korea, India, Indonesia, France and Belgium and they are used broadly in the world. To perform vaccination, 0.5 ML of them was injected into the anterior part of the quadriceps muscle of the infants.

Moreover, according to the medical guidelines of the Islamic Republic of Iran, if a person reports any adverse symptom after vaccination, that symptom is supposed and reported as an adverse event of the vaccination(9). Immediate adverse events including any mortality due to vaccination, hospitalization due to any complications assigned to vaccination, all injection site abscesses and other worrying adverse events should be immediately reported not later than 24 hours after noticing. Vaccination adverse events are recorded in immunization part in care information form in <http://port.health.gov.ir/mfdc/epi/immunization>.

The recorded information includes; The name of the province and medical university in the area, the date of the report, the city, the patients' gender, type of report(urgent vs. non-urgent), hospitalization status (outpatient vs. inpatient), type of reporting health center (urban vs. rural), infants' age, her/his birth weight, birth date, immunization date, type of reaction to vaccination , the vaccine name, vaccine serial number, date of receiving the vaccine, the name of the institute or factory producing the vaccine , adverse event incidence date, the patients' visit date ,their mothers' age in the time of pregnancy , treatment procedure (recovery, being treated, lasting adverse event, death, others), final diagnosis and adverse event categorization (vaccine reaction, error in the vaccination program, simultaneous injection response, unknown). Since infants' recording information form was used to gather the required data and the data analysis was done in groups, there was not any ethical problem in this study; moreover, the researchers considered themselves to be committed to research ethics as well.

Finally, STATA version 12 used to analyze the data. After all, percentage, mean standard deviation and chi-square test were used to describe the data and to investigate the studied variables. Significance level was considered to be $p < 0.05$.

Results

The results showed that among 4249050 infants who received DPT in 2013, 10464 adverse events (about %0.3) and among 4230870 infants received Pentavalent in 2015, 17561 adverse events (about%0.3) were reported throughout the country. The results also showed that more than half of the infants who experienced DPT adverse events (53.36%) were male and about 61.53% lived in rural areas (Table1). In addition, the results showed that the average birth weight of these infants were 3160 ± 487 g and 3202 ± 455.2 g and their average gestational age were 38.4 ± 1.51 and 38.5 ± 1.31 weeks for DPT and Pentavalent vaccines, respectively.

Moreover, the results showed that Mazandaran (15.74%), Ghazvin (11.25%), Golestan (9.12%) and Zanzan (8.44%) have reported the highest and Chaharmahal & Bakhtiari (0.08%), Hormozgan & Bushehr (0.21%), Kurdistan and South Khorasan (0.023%) have reported the least number of vaccination adverse events, respectively. The highest number of DPT adverse events was reported from Mazandaran (17.27%), (13.47%) and Qazvin (11.55%) and the lowest one was reported from Chaharmahal & Bakhtiari (0.03%), South Khorasan (0.11%), Bushehr and Kurdistan (0.16%), respectively. Moreover, the highest number of Pentavalent adverse events was reported from Mazandaran (14.83%), Qazvin (11.05%). And Zanzan (8.01%) and the lowest one was reported from Chaharmahal & Bakhtiari (0.11%) Hormozgan (0.22%), Bushehr and Kurdistan (0.27%), respectively (Table2).

The dispersion of the DPT and Pentavalent adverse events in different parts of the country is shown using geographical information system in figures 1 & 2.

The results also showed that high fever (47.4%) and mild localized complications (31.68%) were reported to be the most frequent events for DPT and Pentavalent respectively. Therefore, although more adverse events were reported for Pentavalent (17561 vs. 10464 cases) compared to DPT, most of Pentavalent reported adverse events were mild, whereas those of DPT were mostly high fever (Fig3).

Last but not the least, according to the results, only 3% of the adverse events in both vaccines led to the infants' hospitalization. Vaccine adverse event categorization in both DPT and Pentavalent showed that the largest category belonged to vaccine reaction (about 95%). The results also indicated that there was a

significant relationship between the kind of vaccine and the type of reaction, adverse event categorization and the infants' place of residence ($p < 0.05$). However, there was no significant relationship between the kind of vaccine and the infants' gender or their hospitalization status. ($P < 0.05$) (Table 3).

Discussion

Although vaccines used in the country immunization program are safe and very effective, no vaccine is completely safe and there might be some adverse events following immunization using any of them (12). On the whole, the amount of adverse events following immunization are low in Iran and most of which are reported to be mild and temporary and are mostly removed without any medical treatment (13). The results showed that the general incidence of adverse events in DPT and Pentavalent were 0.2% and 0.3%, respectively. The high fever and mild localized complication were reported to have the highest incidence in DPT (47.7%) and Pentavalent (31.68%) among other adverse events.

Firstly, it seemed that Pentavalent adverse events number was more than the DPT ones (0.3% vs. 0.2%), but a closer look at the results revealed that most of the Pentavalent reported adverse events were localized and mild, whereas those related to DPT were mostly associated to high and severe fever. On the other hand, the increase in the Pentavalent adverse events reported in 2015 compared to DPT ones reported in 2013 could be justified through the general increase in the number of adverse events reported throughout the country and increasing the ability of the care and health system in identifying and recording more vaccine adverse events in 2015 compared to 2013. Moreover, the results showed that the most frequent adverse events reported were high fever (47.4%) and localized mild events (31.68%) for DPT and Pentavalent and the highest number of adverse events (about 95%) was associated to reactions to the vaccines in general. The study also showed that there was a significant relationship between the kind of vaccine with the type of reaction, adverse events categorization, the infants' gender and place of residence ($p < 0.05$).

In fact, at least one out of four infants having received the vaccines showed some kinds of adverse events which were mostly associated to fever (14). Fever could generally be produced after receiving all kinds of vaccines. This study showed that high fever was the most common adverse event of DPT (%47.4) whereas it was 28.15% for Pentavalent. Severe localized events were reported to be 13.16% in DPT whereas this was half for Pentavalent (about 7.83%). The convulsion cases due to high fever reported to be similar in both vaccines; but vomiting and diarrhea were reported to be much more in DPT compared to Pentavalent. (8.2% vs. 1.58%). Moreover, injection site abscess was reported to be more in Pentavalent than DPT (3.28% vs. 1.58%).

Similarly, in studies by Sharifi et al. (9) and Ayatollahi et al. (15) High fever was reported to be the most frequent adverse event of DPT vaccine. Mansour et al. in New Zealand reported longtime crying among infants who had received DPT (16). Al-Jadiryin in Iraq reported pain and inflammation as the most common events of DPT (17). Barkin et al. reported that 54% of the infants received the vaccine showed fever as the most common event (18). In a study by Suser et al, localized pain, redness, fever and edema

were reported to be the most common adverse events of DPT(19). The benefits of childhood vaccines far outweigh any potential risks. Significant global data on vaccination showed that lack of Hib vaccination caused a significant amount of disease and mortality among infants. Therefore, WHO strongly recommends global Hib Vaccination(20). Pentavalent vaccination automatically increased the coverage of Hepatitis B and Hib immunization(11).

In addition, the results of different studies show that pentavalent vaccine was safe and tolerable and possessed a high level of immunizing for all molecular antigens and some biological reactions(21-24). This vaccine was tested for 10 years from 2002 (when its use started in Ghana) to 2012 (when its use started in India) in some Asian countries(24). The results of these studies showed that the most common reported adverse event of Pentavalent was localized mild events. A study by Indian Institute of Serology showed that local reactions to Pentavalent vaccine included pain, redness and edema in the injection site and its general systematic reactions reported to be fever, unusual crying and irritability(25). Hatami et al. in Tehran, reported fever as the most common adverse event of Pentavalent (71.2%)(13). In a study in the United States of America, high fever was reported to be the most common adverse event of Pentavalent(26) whereas Cunha et al reported hypo-tony as the most common adverse event for DPT and Pentavalent vaccines(27).

Finally, it should be noted that most parents were aware of the fever following vaccination and they preventively gave Acetaminophen to their infants which could decrease their fever and prevent high fever among them; therefore, the incidence rate of this event might be changed due to the parents' interventions(14). Categorizing the vaccine adverse events showed that most of the reported events were associated to the reaction to the vaccine which was in line with Raisi et al. in Shahre Kurd(28) and Parisay et al. findings in Kohkiluyeh va Boir Ahmad(29). In addition, the findings of the study showed that there was not any significant relationship between the infants' gender with DPT and Pentavalent adverse events. However, the possible complications of the vaccines seemed to be more among males compared to the females. This finding was in line with the findings of Reisi et al. in which there wasn't a significant relationship between the gender of the infants and the vaccines' adverse events(28). Moreover, in studies by Paisay et al.(29) and Ayatollahi et al(30). Although there was not a significant relationship between the infants' gender and the vaccines' adverse events, the possible adverse events were reported to be more among males compared to the female which was in line to the findings of this study. However, Nabavi et al. reported that the vaccines' adverse events seemed to be more among females than the male which is in contradiction to the findings of this study(31) (32).

However, severe cases associated with the vaccine adverse events lead to hospitalization which included a very small percentage of the vaccinated infants in comparison to the total number of vaccinated ones. The findings of the study show that only 1.5% of all reported complications in vaccinated infants by DPT and Pentavalent led to their hospitalization and the hospitalized cases numbers were almost the same in both vaccines. In fact, many hospitalization cases can be due to other factors contemporarily existing with vaccination procedure.

Conclusions

Since Pentavalent Vaccination has been started recently in Iran, there were few studies on its associated adverse events. The goal of this study was to compare the adverse events of DPT and Pentavalent Vaccines. The findings showed that some adverse events such as severe localized events, high fever, vomiting and diarrhea and restlessness were less in Pentavalent compared to DPT. Therefore, Pentavalent fewer adverse events, reducing the number of injections and the required injection equipment and finally significant decrease in adverse events following its use showed that this vaccine outweighs DPT and it seems to be more efficient than DPT while considering its costs.

Abbreviations

WHO: World Health Organization DPT: Diphtheria Pertussis Tetanus

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of Kurdistan University of Medical Sciences. The approval number is: IR.MUK.REC.1395.307. We used the patients' recorded information as our source of data and therefore, did not need consent for participation.

Consent for publication

Not applicable

Availability of data and material

The data sets used during the study are available from the corresponding author on reasonable request.

Funding

Not applicable

Authors' contribution

SMZ, FY led data collection. DR, ZKH analyzed data, and GM, ZKH, FY and DR interpreted data. ZKH, GM, and DR drafted the initial manuscript. FY, SMZ and DR were major contributors in writing the manuscript, with critical revisions from ZKH, GM and MA. All authors read and reviewed the final manuscript.

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Conflicts of interests

This study doesn't include any conflict of interest for the authors.

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Tables

Table1-Demographic variables of infants with vaccine complications

vaccine		Variable	
Pentavalent	DPT		
9137(52.1)	5584(53.36)	male	Gender
8399(47.9)	4880(46.64)	female	
8788(50.04)	4025(38.47)	Urban	Location
8773(49.96)	6439961.53)	Rural	

Table 2: The frequency of adverse events DPT vaccine and Pentavalent in different provinces of Iran

Total	Frequency of vaccination complications (%)		Province	ID
	Pentavalent	DPT		
4412(15.74)	2605(14.83)	1807(17.27)	Mazandaran	1
3152(11.25)	1941(11.05)	1211(11.57)	Qazvin	2
2555(9.12)	1146(6.53)	1409(13.47)	Golestan	3
2365(8.44)	1407(8.01)	958(9.16)	Zanjan	4
2202(7.86)	1183(6.74)	1019(9.74)	Khuzestan	5
1676(5.99)	838(4.77)	84(8.04)	Gilan	6
1463(5.22)	994(5.66)	469(4.48)	Fars	7
1457(5.2)	877(4.99)	580(5.54)	Isfahan	8
1346(4.8)	1202(6.84)	144(1.38)	Alborz	9
1109(3.96)	819(4.66)	290(2.77)	East Azerbaijan	10
1087(3.88)	756(4.3)	331(3.16)	Khorasan Razavi	11
937(3.34)	682(3.88)	255(2.44)	Tehran	12
585(2.09)	423(2.41)	162(1.55)	Sistan & Baluchestan	13
500(1.78)	401(2.28)	99(0.95)	Lorestan	14
412(1.47)	250(1.42)	162(1.55)	West Azerbaijan	15
396(1.41)	379(2.16)	17(0.16)	Ardebil	16
382(1.36)	221(1.26)	161(1.54)	Ilam	17
295(1.05)	193(1.1)	102(0.97)	Yazd	18
272(0.97)	179(1.02)	93(0.89)	Hamedan	19
205(0.73)	157(0.89)	48(0.46)	Kermanshah	20
182(0.65)	143(0.81)	39(0.37)	North Khorasan	21
182(0.65)	136(0.77)	46(0.44)	Semnan	22
179(0.64)	126(0.72)	53(0.51)	Kerman	23
165(0.59)	121(0.69)	44(0.42)	Markazi	24
124(0.44)	83(0.47)	41(0.39)	Qom	25
108(0.39)	95(0.54)	13(0.12)	Kohgiluyeh & Boyer-Ahmad	26
64(0.23)	47(0.27)	17(0.16)	Bushehr	27
64(0.23)	53(0.3)	12(0.11)	Southern Khorasan	28
64(0.23)	47(0.27)	17(0.16)	Kurdistan	29
59(0.21)	38(0.22)	21(0.2)	Hormozgan	30
108(0.39)	95(0.54)	13(0.12)	Chaharmahal & Bakhtiari	31
28025(100)	1756(100)	10464(100)	Total country	32

Table3: The relationship between DPT and Pentavalent vaccine characteristics and their adverse events

P-value	Chi-2	Type Vaccine		Variable	
		Pentavalent	DPT		
0.0001	3.8	1375(7.83)	1377(13.16)	Severe localized condition	Type of reaction
		4944(28.15)	4960(47.4)	High fever *	
		1997(11.37)	120(1.15)	Fever	
		5564(31.68)	2018(19.29)	Mild localized condition	
		576(3.28)	170(1.62)	Lyme abscess	
		287(1.63)	186(1.78)	Seizures caused by fever	
		614(3.5)	605(5.78)	Screaming constantly	
		91(0.52)	45(0.43)	Loss of consciousness	
		3(0.02)	2(0.02)	Paralysis of the limb	
		277(1.58)	858(8.2)	Diarrhea and vomiting	
0.0001	263.1	1833(10.44)	123(1.18)	Others	Complaint classification
		718(4.4)	298(2.85)	Programming error	
		15099(92.47)	10110(96.63)	Reactions to Vaccines	
		287(1.76)	4890.46)	Reaction to the injection	
		139(0.85)	4(0.04)	Concurrency	
0.7	0.11	85(0.52)	3(0.03)	Unknown	Hospitalization
		420(2.39)	157(1.5)	Yes	
0.0001	13.19	17141(61.97)	10307(98.5)	No	Report type
		966(5.5)	472(4.51)	Immediate	
		16595(94.5)	9992(95.49)	Non-Immediate	
0.05	4.2	9137(52.1)	5584(53.36)	Male	Gender
		8399(52.1)	4880(46.64)	Female	
0.0001	354	8788(47.9)	4025(38.47)	Urban	Location
		8773(49.96)	6439(61.53)	Rural	

*High fever is defined as higher than 39c

Figures

Figure 1

Prevalence Adverse Events Following Immunization DPT

Figure 2

Prevalence Adverse Events Following Immunization Pentavalent

Figure 3

Comparison of reported adverse events in DPT and Pentavalent Vaccines. *High fever is defined as higher than 39c