

Efficacy Levels of Recombinant Tetravalent Dengue Vaccine (Cyd-Tdv) in Children Aged 2-16 Years: Meta-Analysis

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Abstract

Dengue fever is a type of disease with a high and fast transmission rate, especially in tropical and subtropical regions. One of the dengue fever vaccines developed by Sanofi Pasteur (CYD-TDV) and has undergone phase III clinical trials is the tetravalent dengue vaccine. This study aims to conduct a meta-analysis and review analysis of the effectiveness of the dengue vaccine on the level of efficacy at various age levels based on previously published research results. This research uses a quantitative approach through a meta-analysis study. The data in this study were obtained from multiple sources of scientific literature in the form of research articles published in national and international journals. Data was collected online through Google Scholar, PubMed, ProQuest, Cochrane Library, and Scopus—a literature search from various sources using the keyword dengue vaccine. Data analysis was performed with the distinct stages of the study sample, effect size heterogeneity testing, calculating summary effects, calculating p-values, and determining and plotting publication bias/trim-fill analysis. The research results showed that administration of the tetravalent vaccine (CYD-TDV) to children aged 2-16 years had a moderate relationship with a Random Effect value (r_{RE})=0.400. The efficacy level of the CYD-TDV dengue vaccine significantly impacts patients who are given the vaccine regularly at certain time intervals ($I^2=4.46\%$).

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1. INTRODUCTION

Dengue fever is a disease with a high and rapid transmission rate, especially in tropical and subtropical areas (Syamsir & Pangesty, 2020). Dengue fever can often cause clinical conditions ranging from nonspecific viral syndromes to fatal and severe hemorrhagic disorders. The estimated number of dengue fever cases worldwide reaches 390 million cases of infection that occur every year (Swanstrom et al., 2018), of which around 100 million are associated with clinical manifestations. Most cases occur in dengue endemic areas, especially Asia, India, Central and South America, and Africa WHO in (Skipetrova et al., 2018). Dengue infection can be caused by any of four serotypes of the virus (DENV-1, DENV-2, DENV -3, and DENV-3).DENV-4), leading to a series of clinical findings: subtle or mild febrile illness; classic dengue fever (DF), and the life-threatening conditions dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) (Dayan et al., 2014; Manoff et al., 2019).

One of the dengue vaccines developed by Sanofi Pasteur (CYD-TDV) and undergoing phase III clinical trials is the tetravalent dengue vaccine (Harenberg et al., 2013). The results showed that Dengvaxia™ worked differently based on initial serostatus compared to initial seropositive individuals (Morelli et al., 2012). Responders who were seronegative at baseline had lower vaccine efficacy against virologically confirmed symptomatic dengue fever within 25 months after the first vaccine dose and an increased risk of hospitalization

for dengue fever and severe dengue fever starting approximately 30 months after the first dose. Based on these findings, WHO recommends that countries considering vaccination with Dengvaxia™ as part of a dengue control program implement pre-vaccination screening strategies to limit vaccination to dengue-seropositive individuals (Manoff et al., 2019). Existing research focuses on measuring neutralizing antibodies (NAb) as immune protection against subsequent dengue infection (Waickman et al., 2019) but data from Phase IIb and Phase III trials of the Sanofi-Pasteur vaccine product (Dengvaxia R) show differences between vaccine efficacy and Nab titers (Capeding et al., 2014).

Juraska et al's study reported that a phase 3 placebo-controlled trial of the CYD-TDV vaccine (Dengvaxia) was evaluated in children aged 2-14 years (CYD14) and 9-16 years (CYD15), demonstrating vaccine efficacy / Vaccine Effectiveness (VE) respectively. - 56.5% and 60.8%, respectively, for symptomatic virologically confirmed dengue fever (Juraska et al., 2018). concluded that dengue vaccine (CYD-TDV) is effective when given three injections at 0, 6, and 12 months in Asia, and endemic children aged 2–14 years have a good safety profile (Capeding et al., 2014). This study aims to conduct a meta-analysis and review analysis of the effectiveness of the use of the dengue vaccine on the level of efficacy at various age levels based on previously published research results to obtain accurate results regarding the most appropriate type of use of the dengue vaccine based on the age level of dengue fever sufferers.

2. RESEARCH METHOD

This research uses a quantitative approach through meta-analysis studies. A meta-analysis was conducted to examine the magnitude of the effect of the effectiveness of the dengue fever vaccine on the efficacy level based on patient age. The stages of the meta-analysis study that will be carried out are (1) determining and studying the research topic, (2) collecting several research results with appropriate titles from various sources, (3) calculating the effect size, (4) identifying the size of the heterogeneity effect, (5)) make interpretations of research results and (6) make conclusions based on the results of the analysis carried out (Waluyohadi, 2019).

Data source

Search for literature from various sources using the keyword dengue vaccine. The data in this research was obtained from various scientific literature sources in the form of research articles that have been published in national and international journals. Data was collected online via Google Scholar, PubMed, ProQuest, Cochrane Library, and Scopus.

Article Eligibility Criteria

The criteria used to filter articles for meta-analysis are (1) articles published and accessible online, (2) research articles sourced from Google Scholar, PubMed, ProQuest, Cochrane Library, and Scopus, and (3) research articles which discusses the dengue fever vaccine (CYT-TDV), (4) research articles published in 2011-2020, (5) research articles which discuss and report data on the use and efficacy of the dengue vaccine (CYT-TDV), (6) research articles are not limited to the author's country of origin, (7) articles report type data and control group data in dengue vaccine testing.

Sample and Data Collection

Data collection was carried out online via Google Scholar, PubMed, ProQuest, Cochrane Library, and Scopus. Searches are carried out by visiting various websites, namely <https://scholar.google.com>, <https://pubmed.ncbi.nlm.nih.gov>, <https://www.proquest.com>, <https://www.cochranelibrary.com>, <https://www.scopus.com> with the keywords “dengue

vaccine” and “CYD-TDV vaccine.” with the keywords "dengue fever vaccine" and "CYD-TDV vaccine". Initial results obtained from 112 articles discussing dengue vaccines, then the articles were reviewed using predetermined criteria to obtain articles to be analyzed. Ultimately, four articles met meta-analysis criteria. The stages for selecting articles that meet the requirements are presented in Figure 1.

Data analysis

Data analysis in this research was carried out in stages: (1); characteristics of the research sample; (2) effect size heterogeneity test; (3) calculating summary effects; (4) calculate the p value; and (5) determine and plot publication bias/trim-fill analysis. Data analysis in this study used group contrast meta-analysis based on Risk Ratio (RR) then the research results were interpreted based on the magnitude of the Cohen effect.

3. RESEARCH RESULTS AND DISCUSSION

Research result

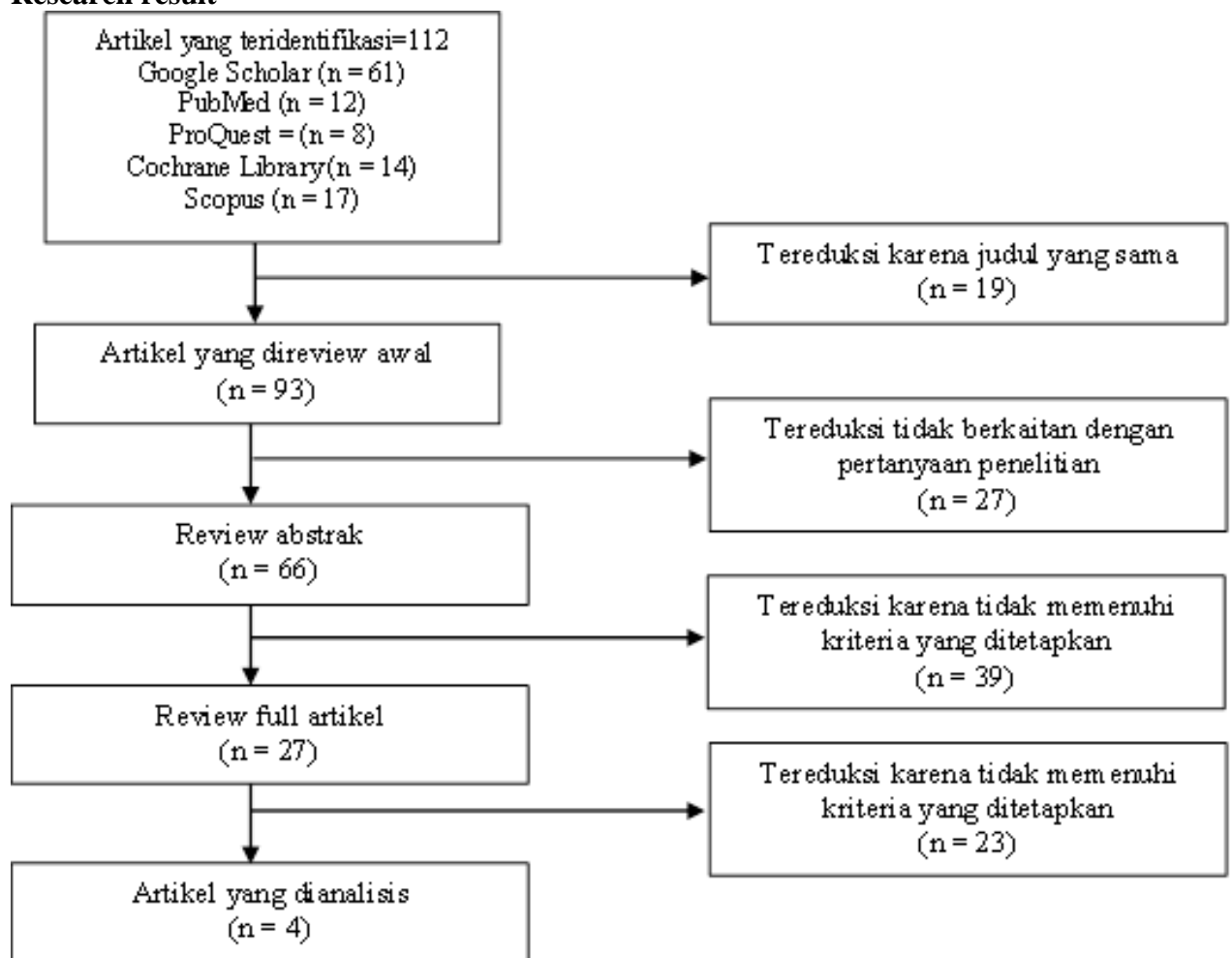


Figure 1. Flow chart of articles that meet meta-analysis requirements

A meta-analysis study was conducted on 4 articles that met the inclusion and exclusion requirements with the following article characteristics.

Table 1. Characteristics of studies that met meta-analysis criteria

No	Writer	Design (Phase)	Age (Years)	Country	Duration (Months)	Treatment	Control
1	(Capeding et al., 2014)	Randomized controlled trial (RCT) Phase III	2 to 14	Indonesia, Malaysia, Philippines, Thailand, Vietnam	6	CYD-TDV	Placebo
2	(Villar et al., 2015)	Randomized controlled trial (RCT) Phase III	9 to 16	Latin America	25	CYD-TDV	Placebo
3	(Sabchareon et al., 2012)	Randomized, controlled / IIb	4 to 11	Thailand	25	CYD-TDV	rabies vaccine or placebo
4	(Biswal et al., 2019)	Randomized controlled trial (RCT) Phase III	4 to 16	Asia & Latin America	3	CYD-TDV	Placebo

Table 1 shows that there are 4 studies that meet the inclusion and exclusion criteria which will then be meta-analyzed. These various studies show various characteristics, namely the testing phase, age and duration of the dengue vaccine trial.

Heterogeneity Test

Heterogeneity tests are carried out to determine the level of diversity of data obtained from each study to be analyzed. The results of the heterogeneity test using JASP software are presented in Table 2 below.

Table 2. Heterogeneity test results; fixed and random effects

	Q	df	p
Omnibus test of Model Coefficients	57,232	1	< .001
Test of Residual Heterogeneity	4,678	3	0.197

Note. p -values are approximate.

Summary Effect/Mean Effect Size

Summary effect testing was carried out to determine the level of correlation between the variable Recombinant Tetravalent Dengue Vaccine (CYD-TDV) in children and the level of efficacy based on the random effect correlation value.

Table 3. Coefficients

	Estimate	Standard Error	z	p	95% Confidence Interval	
					Lower	Upper
intercept	0.400	0.053	7,565	< .001	0.296	0.503

Table 3. Coefficients

Estimate	Standard Error	z	p	95% Confidence Interval	
				Lower	Upper

Note. Wald test.

The results of the analysis using the random effect model show that there is a significant positive correlation between the use of the CYD-TDV vaccine and the level of efficacy in children aged 2-16 years. This is based on the test values obtained. The effectiveness of the CYD-TDV dengue fever vaccine on the efficacy level is in the medium category with correlation values (Cohen, 1988). Furthermore, the distribution of effect sizes from each study is in the following forest plot. ($z = 7.565, p < 0.001, 95\% CI, [0,296; 0,503]$) *Random Effect* (\bar{r}_{RE}) = 0,400

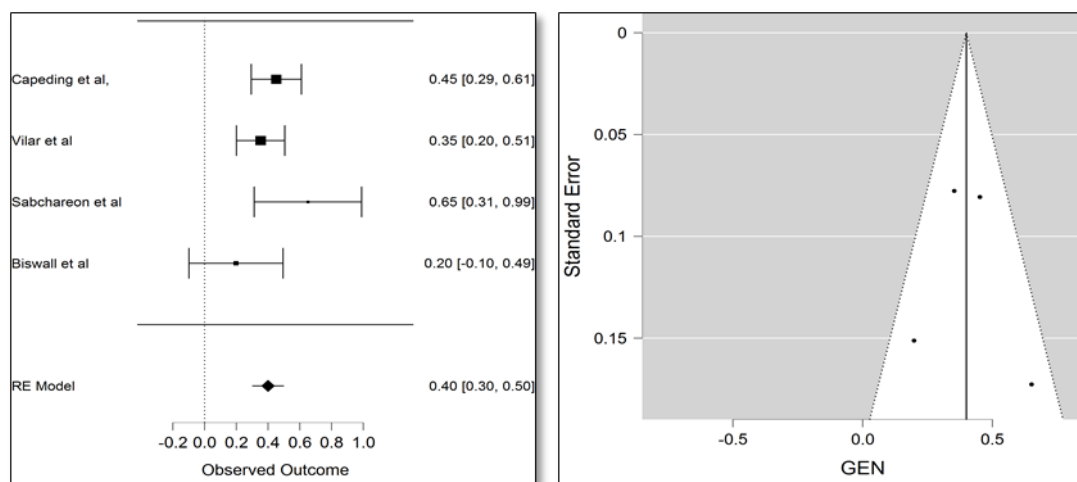


Figure 2. Forest Plots Distribution of Effect Sizes and Fubbel Plots

Based on the forest plot image, it can be seen that the effect of studies size analyzed varied in magnitude between 0.20 to 0.65, then publication bias analysis was carried out fork now there is bias from everyone studies which is analyzed. Picture of *Funnel Plots* difficult show whether the plot is symmetrical or not so the Egger test is needed to test the symmetry of the plot.

Publication Bias based on Egger test scores and *Fail-safe N*

The analysis results show the value. Therefore $z = 0,285$ dan $p - value > 0,05$ atau $0,776 > 0,05$ can It was concluded that there was no problem of publication bias in the meta-analysis study conducted.

Table 4. Regression test for Funnel plot asymmetry ("Egger's test")

	z	p
sei	0.285	0.776

Additionally, based on value of *Fail-safe N*, obtained $K = 4$, so $5K + 10 = 5(4) + 10 = 30$. Mark The fail-safe N obtained was 82.00 with a target significance. Due to the *Fail-safe N* value, it can be concluded that there is no problem of publication bias in the meta-analysis study carried out. $0,05$ dan $p - value < 0,001 . > 5K + 10$ atau $82,00 > 30$

3.1. Discussion

The dengue vaccine that is widely used today is Dengvaxia by Sanofi-Pasteur (Herdady & Mustarichie, 2018). This vaccine contains live, weakened tetravalent viruses, namely DENV 1, 2, 3 and 4. The Dengvaxia vaccine is expected to cause a humoral response to proteins in the body so that it can cause a protective immune response against the dengue virus (Khetarpal and Khanna in Herdady & Mustarichie, 2018). This vaccine has been evaluated for safety and efficacy in phase-3 trials. Dengvaxia obtained the first license in 2015 based on phase-3 clinical trials, namely the CYD14 clinical trials conducted in Asia and CYD15 conducted in Latin America. Both tests involved more than 30,000 participants aged 2-16 years. Vaccine efficacy measurements were carried out after 1 year of complete vaccine administration at 59.2% (Capeding et al., 2014; Villar et al., 2015). The results of the clinical trial concluded that hospitalizations due to dengue increased after the third year of observation in the age group under 9 years, whereas for those aged 9 years and over, there was a decrease in the rate of hospitalizations in the first 2 years of the clinical trial, namely 82% and a decrease the incidence of severe dengue is 93%. Therefore, the license states that the vaccine is only given to individuals aged 9-45 years (WHO in Herdady & Mustarichie, 2018)).

The Chimera vaccine (ChimeriVax) is a vaccine developed from a live attenuated virus. This vaccine was developed through genetic engineering, namely by inserting the Dengue virus envelope and membrane genes into the yellow fever virus (YF 17D). YF 17D is used as a framework because this virus is closely related (genus Flavivirus) and has been tested for safety. (Marbawati & Wijayanti, 2014).

Based on the analysis results, a Random Effect value (r_{RE}^-)=0.400 was obtained, which indicates that the level of efficacy of administering recombinant tetravalent dengue vaccine (CYD-TDV) to children aged 2-16 years is in the medium category. This finding is certainly in line with the research results of Capeding et al. (Capeding et al., 2014) that the CYD-TDV vaccine is efficacious when given three injections at 0, 6 and 12 months to children aged 2–14 years in endemic areas. in Asia, and has a good safety profile. A study conducted by Rodrigues et al., found that CYD-TDV had 60% efficacy against four DENV serotypes after the third vaccine dose and during 13 months of follow-up (Rosa et al., 2019). Vaccination can reduce the incidence of symptomatic infections and hospitalization at home. disease and has the potential to provide public health benefits.

Although there is no evidence that CYD-TDV causes disease, administration of CYD-TDV to a subgroup of individuals who have never had dengue fever may result in that group being more susceptible to secondary episodes of severe dengue fever. Use of this vaccine in a subgroup of seronegative children may result in individuals being susceptible to one or more serotypes for which vaccine immunogenicity is low because CYD-TDV does not produce a balanced immune response among viral serotypes. If a person comes into contact with wild viruses of this serotype with low immunogenicity, severe cases of dengue fever can occur due to increased viral response (Rosa et al., 2019).

The results of statistical analysis show that the correlation between administering the CYD-TDV vaccine and the efficacy level is 93.54% ($I^2=4.46\%$). These results indicate that the level of efficacy of the CYD-TDV dengue vaccine has a significant impact on patients who are given the vaccine regularly at certain time intervals. These results are in line with the findings of Villar et al (2015) that administering the tetravalent vaccine (CYD-TDV) to children has a good level of efficacy against all four

serotypes, including serotype 2, 80.3% efficacy against hospitalized patients for dengue and 95.5%. % against severe dengue was observed over a 25-month period. A higher efficacy rate was observed in children with seropositive status at baseline than in those with seronegative status (83.7% vs. 43.2%).

The funnel plots image shows a level of symmetry which indicates that there is no publication bias from the results of the various studies used in the meta-analysis study. These results are linear with Egger test values ($z=0.285$ and "p-value>0.05) and Fail-safe $N>5K+10$ ($82>30$), which shows that these findings can be used as a new conclusion regarding the level of efficacy of using the CYD-TDV dengue vaccine in children aged 2-16 years.

4. CONCLUSION

Giving the tetravalent vaccine (CYD-TDV) to children 2-16 years old has a relationship with the moderate category with a Random Effect value (r_{RE})=0.400. The efficacy level of the CYD-TDV dengue vaccine has a significant impact on patients who are given the vaccine regularly at certain time intervals ($I^2=4.46\%$).

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