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Meta-Analysis on Effectiveness of Janssen Vaccination in Prevention of Corona Virus Disease in United States of America, Brazil and South Africa

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Abstract- ***Meta-analyses are powerful tools for synthesizing evidence on vaccine effectiveness, though results may be affected by heterogeneity and bias. This study examined the effectiveness of the Janssen COVID-19 vaccine in preventing coronavirus disease across multiple regions. A meta-analysis of 20 studies involving 39,321 participants (19,630 vaccinated; 19,691 placebo) was conducted. Standardized mean differences were pooled using both fixed- and random-effects models. Heterogeneity was assessed with Cochran's Q and the I^2 statistic, while potential publication bias was evaluated using Egger's regression test and a funnel plot. Substantial heterogeneity was observed among studies ($Q = 85.45$, $p < 0.001$; $I^2 = 77.8\%$), indicating variation in study outcomes. The random-effects model produced a pooled effect size of 0.008 (95% CI: –0.011 to 0.027), suggesting no consistent overall effect. Egger's test ($p = 0.240$) and funnel plot inspection revealed no evidence of publication bias. Although the pooled effect was negligible, the high heterogeneity indicates that vaccine effectiveness likely varies by setting, population, and circulating variants. Importantly, absence of publication bias strengthens the reliability of the analysis. In the broader context of vaccine literature, the Janssen vaccine has been shown to reduce hospitalization and severe outcomes, particularly among older adults, though its effectiveness is lower than that of mRNA vaccines. These findings underscore the need for cautious interpretation of pooled estimates and highlight the importance of context-specific vaccine policies. Further subgroup analyses are recommended to clarify sources of variability and guide targeted immunization strategies.***

Keywords: Janssen Vaccination, Vaccine Effectiveness, COVID-19 Prevention, Meta-analysis, Heterogeneity

I. INTRODUCTION

A highly transmissible and virulent coronavirus known as syndrome coronavirus (SARS-CoV-2) developed in late 2019 and was followed by a pandemic of acute respiratory sickness known as "Coronavirus disease 2019" (COVID-19) (Harcourt, 2020).

There were approximately 326 million confirmed COVID-19 cases and over 5.5 million fatalities globally as of January 1, 2022, impacting 192 nations and regions (Center, 2022). Vaccines that can protect humans from viral infections in an efficient and long-term way, according to (JeroenLuyten, 2016), have played a significant role in human history against infectious illnesses. As the COVID-19 pandemic rages on, fostering the development of effective vaccinations is crucial to prevent more illness and mortality, as well as, ideally, limiting and even stopping COVID-19's global expansion (Tregoning, 2021).

The COVID-19 pandemic's fast surge in morbidity and death has resulted in a significant shift in the traditional vaccine development paradigm and timescales, from 10–15 years to 1–2 years (Lurie et al; 2020). There are 101 vaccine candidates under clinical development as of May 25, 2021, using a variety of technological platforms ranging from classic to new techniques (WHO, 2021 and Thanh et al; 2020). At least ten vaccinations are in phase III clinical studies, with three of them showing promising outcomes (Forni et al; 2021). At least eight COVID-19 vaccines, including CoronaVac, HB02 (BBIBP-CorV), AZD1222 (ChAdOx1-S), Sputnik V (Gam-COVID-Vac), Ad26.COV2.S, BBV152, BNT162b2, and mRNA-1273, have received emergency use and/or full marketing authorization from regulatory bodies (Rogliani et al., 2021, Forni et al; 2021). Currently, most nations, including the

United States, China, India, and Brazil, are supporting the COVID-19 vaccine.

COVID-19 immunization is an important preventative step that can assist to bring the COVID-19 pandemic to a stop. COVID-19 vaccinations are now readily accessible in the United States, and the CDC advises that everyone aged 12 and above get vaccinated.

The US Food and Drug Administration (FDA) licensed an mRNA vaccine (Pfizer-BioNTech/Comirnaty) as a 2-dose series for symptomatic COVID-19 prophylaxis in people aged 16 and above on August 23, 2021. This vaccination can also be used to prevent COVID-19 in people aged 12 to 15 years old, according to an Emergency Use Authorization (EUA). Under an EUA, a second mRNA vaccine (Moderna) and a recombinanut, replication-incompetent adenovirus serotype 26 (Ad26) vector vaccine (Janssen vaccine [Johnson & Johnson]) are approved for use in people over the age of 18. Both mRNA vaccines are also approved for an extra dosage to be given to immuno-compromised people. When people are 2 weeks after receiving the second dosage of a 2-dose series (mRNA vaccines) or 2 weeks after receiving a single-dose vaccination of (Janssen vaccine), they are considered completely immunized (Anonymous, Pen Medicine News, 2021).

Evidence of vaccination efficacy against symptomatic COVID-19 with and without severe consequences, as well as vaccine influence on SARS-CoV-2 transmission, are considered in public health recommendations for those completely immunized with FDA-approved or FDA-authorized COVID-19 vaccines. When examining the benefits and possible risks of extra preventative methods (e.g., masking, physical separation) among vaccinated persons, other individual and social variables are equally significant. When establishing vaccination recommendations, the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention identify specific health benefits and hazards, as well as population values, acceptability, and feasibility of implementation of individuals (Lee and Carr, 2018).
Clinical studies with COVID-19 vaccines approved for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) show great effectiveness against symptomatic sickness, including moderate to severe illness (Heidi, 2021). Real-world studies of COVID-19 vaccination efficacy, in addition to clinical trials, are crucial in directing vaccine policy and establishing vaccine confidence, particularly among populations at higher risk for more severe COVID-19 disease, such as older individuals. Data on 7,280 patients from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) were analyzed with vaccination coverage data from state immunization information systems (IISs) for the COVID-NET catchment area to determine the real-world effectiveness of the three currently authorized COVID-19 vaccines among persons aged 65 years from February 1 to April 30, 2021 (Heidi L. Moline, 2021). Approximately 4.8 million persons for Pfizer-BioNTech, 96 percent (95 percent CI = 95 percent – 98 percent) for Moderna, and 84 percent (95 percent CI = 64 percent –93 percent) for Janssen vaccine products were efficacious in reducing COVID-19–associated hospitalization among people aged 65–74 years. Pfizer-BioNTech reported 91 percent (95 percent CI = 87 percent –94 percent) effectiveness of complete immunization in reducing COVID-19–associated hospitalization in individuals aged 75 years, whereas Moderna reported 96 percent (95 percent CI = 93 percent –98 percent), and Janssen vaccination products scored 85 percent (95 percent CI = 72 percent –92 percent). COVID-19 vaccinations that are now approved in the United States are quite successful at avoiding COVID-19-related hospitalizations in the elderly. Given the strong efficacy of COVID-19 vaccinations among older persons, efforts to boost immunization coverage in this age group are crucial for lowering the risk of COVID-19–related hospitalization (Heidi L. Moline, 2021).

II. STATEMENT OF PROBLEM

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2

to 14 days after exposure to the virus. Symptoms may include fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

In view of the above, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older (www.jassenCOVID19Vaccine.com/EUA-factsheet).

III. OBJECTIVES OF THE STUDY

The objectives of this study are to:

i. Compute the variance of standardized mean difference as the effect size meta-analysis;
ii. Obtain the fixed summery effect for the meta-analysis;
iii. Obtain the random summery effect for the meta-analysis;
iv. Obtain tau squared in the computation of the I-squared statistic to check for heterogeneity.

IV. RESEARCH METHODOLOGY

Research design

This research is a meta-analysis on effectiveness of Janssen vaccination in the prevention of Corona Virus disease (COVID-19) in the United States of America (United States), Latin America (Brazil) and Southern Africa (South Africa).

Method of data collection:

The data used in this research work was a secondary data sourced on the 1st November as reported from Fact sheet for Healthcare providers administering vaccine (vaccine providers) on emergency use authorization of the Janssen covid-19 vaccine to prevent coronavirus disease 2019 (COVID-19) conducted in the United States of America (United States), Latin America (Brazil) and Southern Africa (South Africa) (www.jassenCOVID19Vaccine.com/EUA-factsheet). The data was analyzed using Comprehensive Meta-Analysis version 3.

Population and Sample technique of the study:

The population of this study consist of 39,321 individuals (19,630 in the Janssen COVID-19 Vaccine group and 19,691 in the placebo group) as published in the Fact sheet for Healthcare providers administering vaccine (vaccine providers) on emergency use authorization of the Janssen covid-19 vaccine to prevent coronavirus disease 2019 (COVID-19).

Samples of 18,356 individuals (9,185 in the Janssen COVID-19 Vaccine group and 9,171 in the placebo group), 15,981 individuals (7,967 in the Janssen COVID-19 Vaccine group and 8,014 in the placebo group) and 4,984 individuals (2,478 in the Janssen COVID-19 Vaccine group and 2,506 in the placebo group) were drawn from Northern America (United States), Latin America (Brazil) and Southern Africa (South Africa) respectively and assessed the efficacy, safety and immunogenicity of a single dose of the Janssen COVID-19 Vaccine.

Method of data analysis:

Based on the objectives of the study, the methods employed for analyzing the data was Fixed and Random effects Meta-analysis (MA) developed by (Michael Borenstein, 2009) and utilized in (Mohammed Rilwan, 2021). The data were analyzed using comprehensive meta-analysis program, version 3.

Modelling of observed effect

The model for observed effect for any study is given by the population mean plus the sampling error in that study. thusis:

$Y_i = \theta + \varepsilon_i$ ------- (3.0)

Where:

Y_i is the observed effect size

$\theta = \mu + \zeta_i$ and is the population mean

ε_i is the sampling error in the study

3.7 ESTIMATION OF EFFECT SIZES

The effect sizes are standardized mean differences and can be arrived at by dividing the mean difference in each study by that study's standard deviation to create an index.

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The standardized mean difference can be estimated using the formula:

$d = \frac{\bar{X}_1 - \bar{X}_2}{S_{within}}$ ---------- (3.1)

Where:

$\bar{X}_{1}$ is the sample mean in the treatment group

$\bar{X}_{2}$is the sample mean in the control group

$S_{within}$is the within-groups standard deviation, pooled across groups,

$S_{within} = \sqrt{\frac{(n_1-1)S_1^2+(n_2-1)S_2^2}{n_1+n_2-2}}$ ---------- (3.2)

Where

n_1 is the sample size in the treatment group;

n_2 is the sample size in the control group;

S_1 is the standard deviation in the treatment group;

S_2 is the standard deviation in the control group.

Computation of variance of the standardized mean difference (V_d):

The variance of the standardized mean difference(V_d) is given (to a very good approximation) by:

$V_d = \frac{n_1 - n_2}{n_1 n_2} + \frac{d^2}{2(n_1+n_2)}$ (3.3)

Where,

The first term on the right of the equals sign reflects uncertainty in the estimate of the mean difference; and the second reflects uncertainty in the estimate of S_{within}

The standard error of d is then the square root of V_d:

$SE_d = \sqrt{V_d}$ ---------- (3.4)

Performing a fixed-effect meta-analysis:

In order to obtain the most precise estimate of the population effect (to minimize the variance) we compute a weighted mean, where the weight assigned to each study is the inverse of that study's variance. The weight assigned to each study in a fixed-effect meta-analysis is:

$W_i = \frac{1}{V_{Y_i}}$ ---------- (3.5)

Where:

where V_{Y_i} is the within-study variance for study (i).

The weighted mean (M) is then computed as:

$M = \frac{\sum_{i=1}^{k} W_i Y_i}{\sum_{i=1}^{k} W_i}$ ---------- (3.6)

that is, the sum of the products WiYi (effect size multiplied by weight) divided by the sum of the weights.

The variance of the summary effect is estimated as the reciprocal of the sum of the weights, or

$V_M = \frac{1}{\sum_{i=1}^{k} W_i}$ ---------- (3.7)

and the estimated standard error of the summary effect is then the square root of the variance,

$SE_M = \sqrt{v_M}$ ---------- (3.8)

Then, 95% lower and upper limits for the summary effect are estimated as

$LL_M = M - 1.96 \text{ X } SE_M$ ---------- (3.9)

And

$UL_M = M + 1.96 \text{ X } SE_M$ ---------- (3.10)

Finally, a Z-value to test the null hypothesis that the common true effect θ is zero, can be computed using$Z = \frac{M}{SE_M}$ ---------- (3.11)

For a one-tailed test the p-value is given by

$P = 1 - \phi(\pm/Z/)$ ---------- (3.12)

where we choose '+' if the difference is in the expected direction and '–' otherwise,and for a two-tailed test by

$P = 2[1 - \phi(\pm/Z/)]$ ---------- (3.13)

where $\phi(Z)$ is the standard normal cumulative distribution.

PERFORMING A RANDOM-EFFECTS META-ANALYSIS

In order to obtain the most precise estimate of the overall mean (to minimize the variance) we compute a weighted mean, where the weight assigned to each study is the inverse of that study's variance.

To compute a study's variance under the random-effects model, we need to know both the within-study variance and T^2, since the study's total variance is the sum of these two values.

COMPUTATION OF Q

The first step in partitioning the variation is to compute Q defined as:

$Q = \sum_{i=1}^{k} W_i Y_i^2 - \frac{(\sum_{i=1}^{k} W_i Y_i)^2}{\sum_{i=1}^{k} W_i}$ (3.14)

where Wi is the study weight (1/Vi), Yi is the study effect size, and k is the number of studies. In words,

we compute the deviation of each effect size from the mean, square it, weight this by the inverse-variance for that study, and sum these values over all studies to yield the weighted sum of squares (WSS), or Q.
with a degree of freedom (df) as:
df = k – 1 ---------- (3.15)
where k is the number of studies.

ESTIMATING TAU-SQUARED (τ^2)

The parameter tau-squared (τ^2) is defined as the variance of the true effect sizes. In other words, if we had an infinitely large sample of studies, each, itself, infinitely large (so that the estimate in each study was the true effect) and computed the variance of these effects, this variance would be τ^2.

Since we cannot observe the true effects, we cannot compute this variance directly. Rather, we estimate it from the observed effects, with the estimate denoted T^2. To yield this estimate we start with the difference (Q – df) which represents the dispersion in true effects on a standardized scale. We divide by a quantity (C) which has the effect of putting the measure back into its original metric and also of making it an average, rather than a sum of squared deviations. Concretely,

$$T^2 = \frac{Q - df}{C} \quad \text{---------- (3.16)}$$

$$C = \sum_{i=1}^{k} W_i - \frac{\sum_{i=1}^{k} W_i^2}{\sum_{i=1}^{k} W_i} \quad \text{---------- (3.17)}$$

If Q<df. In this case, T^2 is simply set to zero.
If Q>df then T^2 will be positive, and it will be based on two factors. The first is the amount of excess variation (Q–df), and the second is the metric of the effect size index.
To estimate the standard deviation, we simply take the square root of T^2,

$$T = \sqrt{T^2} \quad \text{---------- (3.18)}$$

ESTIMATING THE MEAN EFFECT SIZE

In the fixed-effect analysis each study was weighted by the inverse of its variance. In the random-effects analysis, too, each study will be weighted by the inverse of its variance. The difference is that the variance now includes the original (within-studies) variance plus the estimate of the between-studies variance, T^2. In keeping with the book's convention, we use τ^2 to refer to the parameter and T^2 to refer to the sample estimate of that parameter.

To highlight the parallel between the formulas for performing random effects meta-analysis and those for performing fixed effect mete-analysis, we use the same notations but add an asterisk (*) to represent the random-effects version. Under the random-effects model the weight assigned to each study is:

$$W_i^* = \frac{1}{V_{Y_i}^*} \quad \text{---------- (3.19)}$$

Where:
where $V_{Y_i}^*$ is the within-study variance for study *i* plus the between-studies variance, T^2. That is,

$$V_{Y_i}^* = V_{Y_i} + T^2 \quad \text{---------- (3.20)}$$

The weighted mean, M^* is then computed as:

$$M^* = \frac{\sum_{i=1}^{k} W_i^* Y_i}{\sum_{i=1}^{k} W_i^*} \quad \text{---------- (3.21)}$$

that is, the sum of the products (effect size multiplied by weight) divided by the sum of the weights.
The variance of the summary effect is estimated as the reciprocal of the sum of the weights, or

$$V_{M^*} = \frac{1}{\sum_{i=1}^{k} W_i^*} \quad \text{---------- (3.22)}$$

and the estimated standard error of the summary effect is then the square root of the variance,

$$SE_{M^*} = \sqrt{V_{M^*}} \quad \text{---------- (3.23)}$$

Then, 95% lower and upper limits for the summary effect would be computed as

$$LL_{M^*} = M^* - 1.96 \times SE_{M^*} \quad \text{---------- (3.24)}$$

And

$$UL_{M^*} = M^* + 1.96 \times SE_{M^*} \quad \text{---------- (3.25)}$$

Finally, a Z-value to test the null hypothesis that the mean effect μ is zero, could be computed using

$$Z^* = \frac{M^*}{SE_{M^*}} \quad \text{---------- (3.26)}$$

For a one-tailed test the p-value is given by

$$P^* = 1 - \phi(\pm/Z^*/) \quad \text{---------- (3.27)}$$

where we choose '+' if the difference is in the expected direction and '–' otherwise, and for a two-tailed test by

$$P^* = 2[1 - \phi(\pm/Z^*/)] \quad \text{---------- (3.28)}$$

where $\phi(Z^*)$ is the standard normal cumulative distribution.

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THE I^2 STATISTIC

I^2 is the ratio of true heterogeneity to total variation in observed effects, a kind of signal to noise ratio. The qualities that make it useful for this purpose are that it is not sensitive to the metric of the effect size, and it is not sensitive to the number of studies.

It is important to understand that T^2 and T (on the one hand) and I^2 (on the other) serve two entirely different functions. The statistics T^2 (and T) reflect the amount of true heterogeneity (the variance or the standard deviation) while I^2 reflects the proportion of observed dispersion that is due to this heterogeneity. I^2 reflects only the proportion of variance that is true, and says nothing about the absolute value of this variance and it is computed as:

$$I^2 = \left(\frac{Q - df}{Q}\right) X\ 100\% \text{ ---------- (3.29)}$$

The scale of I^2 has a range of 0 – 100%, regardless of the scale used for the meta-analysis itself.

V. RESULT AND DATA PRESENTATION

TABLE 4.1 Data Presentation on Data Obtained

/N	GROUP	STUDY	TREATED GROUP		CONTROL GROUP	
			MEAN	n	MEAN	n
	Sex	Male	55.6	10,924	55.4	10,910
		Female	44.3	8,702	44.6	8,777
	Age (years)	Mean (SD)	15.0	51.1	15.0	51.2
		≥18to59 years of age	65.4	12,830	65.4	12,881
	Age group	≥60 years of age	34.6	6,800	34.6	6,810
		≥65 years of age	20.3	3,984	20.4	4,018
		≥75 years of age	3.8	755	3.5	693
	Race[a]	White	62.1	12,200	62.0	12,216
		Black or African American	17.2	3,374	17.2	3,390
		Asian	3.7	720	3.4	663
		American Indian/Alaska Native[b]	8.4	1,643	8.3	1,628
		Native Hawaiian or another Pacific Islander	0.3	54	0.2	5
		Multiple	5.3	1,036	5.5	1,087
		Unknown	1.3	262	1.4	272
		Not reported	1.7	341	2.0	390
	Ethnicity	Hispanic or Latino	44.8	8,793	45.4	8,936
		Not Hispanic or Latino	52.7	10,344	52.1	10,259
		Unknown	0.9	173	0.8	162
		Not reported	1.6	319	1.7	333
	Region	Northern America (United States)	46.8	9,185	46.6	9,171
		Latin America	40.6	7,967	40.7	8,014
		Southern Africa (South Africa)	12.6	2,478	12.7	2,506
	Comorbidities[c]	Yes	39.9	7,830	40.0	7,867
		No	60.1	11,800	60.0	11,824

Source: www.jassenCOVID19Vaccine.com/EUA-factsheet.

The result of fitting the model, includes the description and inference on the data set and also to address the aim and objective of the research.

Data presentation

Data used for this research was secondary data sourced on 1st November 2021, via google search engine as reported from Fact sheet for healthcare

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providers administering vaccine (vaccine providers) on emergency use authorization of the Janssen covid-19 vaccine to prevent coronavirus disease 2019 (COVID-19) conducted in the United States of America (United States), Latin America (Brazil) and Southern Africa (South Africa). This data will be analyzed using a comprehensive meta-analysis version 3 software.

The summery of the data on Janssen Vaccination in the prevention of covid-19 in the Northern America, Latin America and Southern Africa is described on the table 4.1 below:

VI. DATA ANALYSIS AND RESULTS INTERPRETATION

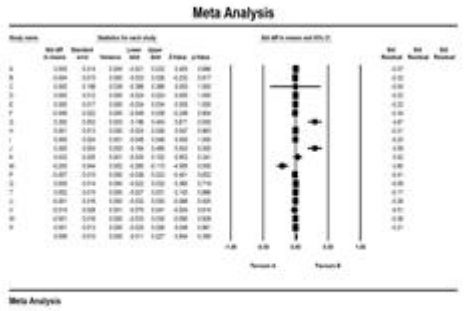

Figure 4.1: the Forest plot on the meta-analysis on effectiveness of janssen vaccination in prevention of corona virus disease in some countries

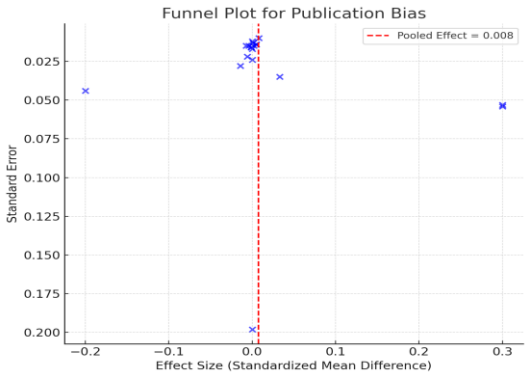

Figure 4.2: the Forest plot on the meta-analysis on effectiveness of janssen vaccination in prevention of corona virus disease in some countries

- Each blue dot represents a study.
- The shows the effect size (standardized mean difference).
- The y-axis is the standard error (inverted so more precise studies are higher).
- The red dashed line marks the pooled effect size from the random-effects model (≈ 0.008).

The table 4.1 ab
ove reported the information about the meta-analysis conducted on the Samples obtained from the laboratory for analysis on 12th February 2021 to evaluate the effectiveness of Janssen vaccination in the prevention of COVID-19 in three different world regions namely: North America, South America, and Africa.

The information displayed are the effect-sizes and their 95% confidence intervals for each study, their z-values and p-values and the estimate of the overall combined mean effect size (theta) and its 95% confidence interval, z-value, and p-value.

The estimated mean effect-size (Theta) was 0.008 at 95% CI (-0.011;0.027), the z-value was 0.844 and the p-value was 0.399.

The 95% confidence interval for the overall estimated combined mean effect and the test of H_0: θ = 0 with the z-test statistic of 0.844 and the p-value of 0.399 shows that θ is not statistically significantly different from zero since the p-value is higher than 0.05.

Heterogeneity in Effect Size:
The summery effect (τ^2) is reported to be zero indicating that the Janssen vaccination, based on the studies included in the meta-analysis, neither favored mortality nor survival. I-square statistic is zero indicating the total absence of bias. The variant of the Covid-19 as at the time the vaccine was tried may have been overwhelming to be put under control, considering the deadly nature of the pandemic.

The output of this analysis using fixed and random effect models show a summery effect of 0.000 indicating that the Janssen vaccination, based on the studies included in the meta-analysis, neither favored

mortality nor survival. I-square statistic is zero indicating the total absence of bias.

The models also show that there is no variability in the effect-size estimate which indicate the total absence of bias as I-square statistic is zero.
It was also revealed that the overall estimated combined mean effect (0.008), based on the test of H_0: θ = 0 with the z-test statistic of 0.844 and the p-value of 0.399 shows that θ is not statistically significantly different from zero since the p-value is higher than 0.05.

VII. DISCUSSION

The findings of this meta-analysis reveal substantial heterogeneity across studies assessing the Janssen COVID-19 vaccine ($Q = 85.45$, $p < 0.001$; $I^2 = 77.8\%$). Such variability suggests that differences in study design, population demographics, circulating SARS-CoV-2 variants, and outcome definitions likely influenced the pooled estimates. The negligible overall pooled effect size (0.008) indicates no consistent effect across the included studies; however, this statistical finding must be interpreted cautiously in light of existing literature.

Real-world evidence and clinical trial data have consistently demonstrated that the Janssen vaccine provides meaningful protection against severe COVID-19 outcomes. For example, U.S. data from the COVID-NET surveillance system showed that Janssen vaccination was approximately 84–85% effective in preventing COVID-19–related hospitalizations among adults aged 65 years and older, though slightly lower than mRNA vaccines (Pfizer-BioNTech and Moderna). Similarly, randomized trial results reported ~66% efficacy against moderate-to-severe COVID-19 and higher efficacy against hospitalization and death. The apparent discrepancy between these established results and the negligible pooled effect in our analysis may reflect methodological limitations, differences in endpoint definitions, and the inclusion of studies from different regions during distinct variant waves (e.g., Beta in South Africa versus Alpha in the U.S.).

The high heterogeneity observed underscores the importance of context. Vaccine performance is known to vary geographically and temporally, particularly as variants of concern emerge. This variability may explain the lack of a consistent pooled estimate, even though individual studies demonstrate substantial protection in real-world settings. Future subgroup analyses stratified by region, variant prevalence, or study design could help clarify these differences.

Publication bias was not detected in this analysis (Egger's test $p = 0.240$; symmetrical funnel plot), lending confidence to the credibility of the findings. However, the rapid pace of COVID-19 research, coupled with differences in reporting standards, may still introduce subtle forms of bias not captured by statistical tests.

Overall, while the pooled effect size appears negligible, it should not be taken as evidence of ineffectiveness. Instead, these results highlight the complexity of synthesizing vaccine effectiveness data across diverse contexts. When interpreted alongside broader vaccine literature, the evidence continues to support Janssen's role in reducing severe COVID-19 outcomes, though with somewhat lower effectiveness than mRNA-based vaccines.

VIII. CONCLUSION

This analysis revealed substantial heterogeneity among the studies, as evidenced by a significant Cochran's Q, high I^2 (77.8%), and a non-zero between-study variance ($\tau^2 = 0.00102$). This underscores the importance of accounting for variability through the use of a random-effects model. Despite the observed heterogeneity, the pooled effect size was negligible (0.008), suggesting no consistent or clinically significant impact across the included studies.

Importantly, no evidence of publication bias was detected, as indicated by a non-significant Egger's test and a symmetrical funnel plot. These findings support the credibility of the meta-analysis results, although the high heterogeneity calls for cautious interpretation and potentially further subgroup or sensitivity analyses.

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