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Meta-analysis

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Fecal shedding and transmission of vaccine−derived poliovirus: A systematic review and meta−analysis

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ABSTRACT

Objective: This review aims to summarize the emergence and transmission of vaccine-derived poliovirus (VDPV) across various geographies, its impacts, and the developments of immunization techniques and vaccines.

Methods: This systematic review and meta-analysis followed Prioritization of Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA) criteria and was registered with Prospective Systematic Reviews (CRD42023389248). We included clinical studies such as randomized controlled trials, cohort studies, case reports and cross-sectional studies accessing the fecal excretion of VDPV. Five independent reviewers selected appropriate and relevant studies from PubMed, ScienceDirect and Google Scholar published before January 2023. Statistical analyses were performed using odds ratios (*OR*) with 95% confidence intervals (*CI*) and a random effects model to address heterogeneity (I^2), with publication bias evaluated via funnel plots and statistical tests.

Results: Out of the 83 initially identified studies, 9 were included in meta-analysis. Participants who received the first dose of monovalent oral polio vaccine (mOPV) did not show statistically significant fecal shedding compared to those treated with the second dose (*OR*: 1.02, 95% *CI*: 0.51-2.03, *P*=0.47). Individuals who received the novel oral polio vaccine (nOPV) significantly reduce virus fecal shedding after the second dose compared to the first dose (OR: 2.95. 95% *CI*: 1.39-6.25, *P*=0.00). Sero-conversion rates do not differ significantly between two doses in participants received mOPV (*OR*:1.10, 95% *CI*: 0.60-2.01, *P*=0.35), meanwhile nOPV exhibit a higher seroconversion rate (*OR*: 0.07, 95% *CI*: 0.01-0.67, *P*=0.01).

Conclusions: This study provides the evidence supporting the clinical efficacy and safety of nOPV compared to mOPV.

KEYWORDS: Oral polio vaccine; Fecal shedding; Vaccine derived polio virus; Novel oral polio vaccine (nOPV); Monovalent oral polio vaccine (mOPV)

1. Introduction

Oral vaccines are widely used to combat the last stronghold of poliovirus. Adverse reactions to oral polio vaccine (OPV) can lead to the transmission of vaccine-derived poliovirus (VDPV). The live attenuated (weakened) poliovirus used in OPV can cause sporadic and paralytic polio[1]. Although rare, the attenuated OPV viruses, which have effectively eradicated polio in most parts of the world, can mutate and regain neurovirulence[2,3].

Improper hand hygiene and the consumption of food and water contaminated with human feces are common causes of polio infection, which occurs when people come into contact with feces[4]. The virus begins to multiply in the nose and throat, then travels to the intestines where it multiplies, enters the bloodstream, and finally reaches the central nervous system, causing paralysis and nerve damage[5]. Among every 200 people who get this disease, 1 person becomes paralyzed. Additionally, 5%-10% of paralyzed people die due to respiratory muscle failure. The continued prevalence of circulating vaccine-derived poliovirus (cVDPV) from the fecal excretion of live poliovirus used as an oral polio vaccine poses a significant obstacle to achieving complete eradication of poliovirus worldwide[6].

The first step was the switch from trivalent oral polio vaccine

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(tOPV) to bivalent oral polio vaccine (bOPV, types 1 and 3) in the April 2016 primary vaccination series[7]. At least one dose of inactivated polio vaccine (IPV) was simultaneously introduced in countries where OPV was used. IPV enhances the protection provided by OPV[8]. IPV does not cause vaccine-induced paralysis. While IPV can result in VDPV, it induces only marginal primary enteric immunity required to stop the replication of live poliovirus on subsequent exposures, regardless of the dose or route of administration[9]. Therefore, control of cVDPV outbreaks relies on the use of homotypic OPV to induce or enhance intestinal immunity and prevent new OPV type 2 transmission[10]. Since the World Health Assembly declared its intention to eradicate polio in 1988, the number of people paralyzed by the poliovirus has decreased by more than 99.9%[11, 12].

The Global Polio Eradication Initiative (GPEI) aimed to reduce the number of countries where wild poliovirus (WPV) is endemic from 125 countries in 1988 to 2 by 2021, reducing the number of cases from over 350,000 to just 2. The eradication of polio has prevented 20 million children from developing paralytic polio[5]. In 2013, the World Health Organization (WHO) recorded 416 cases of wild paralytic poliovirus worldwide[13]. As of mid-2014, the remaining endemic areas of wild poliovirus were confined to vulnerable security zones in Pakistan, Afghanistan, and Nigeria[13]. However, wild poliovirus is frequently exported from these endemic areas to polio-free countries, resulting in polio epidemics. Therefore, the export of wild poliovirus from the last endemic foci remains a threat to polio eradication[14].

Widespread use and continued use of the two polio vaccines, IPV and OPV, have significantly reduced the incidence of paralytic polio[15]. However, as long as this virus exists everywhere in the world, polio cannot be eradicated[16]. GPEI launched an initiative in 2013 to strengthen the containment and eradication of all polioviruses, including WPV, Sabin-strain OPV, and VDPV.

The Sabin-strain OPV and polio vaccines successfully prevent crippling polio in most parts of the world[17]. Enhanced inactivated polio vaccine (eIPV), administered by injection, is used successfully in many parts of the world, but OPV remains the vaccine of choice in other countries, including the United States[18,19]. The main advantages of OPV are its ease of administration and increased "mucosal immunity" due to active viral replication in the gut[20,21]. However, the use of OPV in the United States is associated with rare cases of paralysis, especially when the vaccine is first administered[22]. The eradication of polio requires the elimination of all polioviruses, including WPV and VDPV, from the population. Sabin-strain OPV is the source of VDPV. VDPV may emerge after long-term replication in OPV recipients or long-term transmission among unvaccinated populations[2]. The continued use of OPV after the eradication of polio is incompatible with global eradication goals due to the risk of endemic or contagious spread of the virus. To control VDPV, the eradication of polio requires the development of an OPV eradication plan with GPEI capability. In 2016, Sabin poliovirus type 2 was removed from tOPV and replaced by bOPV (types 1 and 3)[23]. A single dose of the IPV is given at the same time. The clinical development of the novel oral polio vaccine type 2 (nOPV2) is still ongoing, but due to the public health emergency of international concern caused by the outbreak of circulating vaccine-derived poliovirus type 2 (cVDPV2), phase 1 and 2 trials have shown its stability, and WHO has added it to the Emergency Programs List[24].

To date, more than 450 million doses of vaccine have been distributed to control epidemics[14]. Eight clinical studies demonstrating the safety, persistence, and immunogenicity of nOPV2 have been conducted in polio-vaccinated adults and children[25]. Analysis of viruses detected in the stool samples showed that nOPV2 is less likely to develop a neurovirulent phenotype and is genetically more stable than the Sabin OPV2 strain[14].

2. Methods

2.1. Study registration and methods

This study was conducted according to the Prioritization of Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria[26]. The protocol used in this study was registered in the International Registry of Prospective Systematic Reviews (PROSPERO) with the code CRD42023389248.

2.2. Eligibility criteria and search strategy

A literature search of 83 studies was conducted from inception to January 2023 using multiple electronic databases, including PubMed, ScienceDirect, Sci-Hub, and Google Scholar. Time and language restrictions were applied. This review only included clinical trial articles, such as randomized controlled trials, non-randomized cohort studies, case-control studies, and cross-sectional studies, assessing the fecal excretion of VDPV. Reviews on WPV, conference abstracts, case reports, and case series were excluded. Patients with positive fecal poliovirus excretion detected by reverse transcription polymerase chain reaction test (RT-PCR) and rotavirus test were included in the study. The study included research on VDPV and vaccine-associated paralytic poliomyelitis (VAPP)-infected children and adults and new approaches to vaccination. There was no restriction on age, race, occupation, economic status, religion, ethnicity, or underlying medical conditions.

This review also includes studies evaluating various new approaches to reduce cases of vaccine-induced paralytic poliomyelitis. No comparator was used in the study. The primary results of interest were: A) The presence of VDPV induced by OPV; B) The effectiveness of new vaccination approaches to reduce VDPV/VAPP; C) The reduction in fecal shedding of poliovirus due to the switch from tOPV to bOPV and several other new approaches. The searches were conducted by five independent reviewers.

Articles were identified using the keywords: “oral polio vaccine”, “fecal excretion”, “vaccine-derived poliovirus”, “vaccine-associated paralytic polio”, and “inactivated polio vaccine”. Filters retrieved articles by title and abstract after reduplication. The potentially eligible full-text articles were then fully assessed using the above eligibility criteria. Any discrepancies that arose were resolved through scoring by the five judges.

2.3. Data extraction

Data extracted from these studies included the following: the first author, year of publication region, study design, sample characteristics and size, severity of polio cases, intervention (dose, route of administration, duration) and control, follow-up, and the effectiveness and safety of new approaches and interventions.

2.4. Data synthesis and statistical analysis

Odds ratio (*OR*) with confidence interval (*CI*) of 95% were calculated. Depending on the heterogeneity, a random effects model was employed. Higgins I^2 statistics was used to describe heterogeneity of included studies. Visual evaluation of publication bias was conducted using a funnel plot. Possible publication bias was shown by an asymmetric funnel plot. Begg and Mazumdar rank correlation test and Egger’s test of the intercept were employed to determine the presence of publication bias statistically. Meta-Essentials 1.5_01 was used to conduct all statistical tests.

3. Results

A total 83 studies were identified through searches in electronic databases and after evaluating their titles and abstracts, 70 publications were selected, of which 44 were determined to be eligible. Finally, 9 studies were included in the meta-analysis as shown in Table 1. The search flow diagram and selection methodology are summarized in Figure 1.

The researches were carried out in various countries, including Mexico, India, Bangladesh, and the United States. All the studies enrolled infants, kids, and adults up to the age of 55. We considered OPV side effects, such as mild to severe bowel movements. Two doses of OPV were administered to the groups, and the levels of fecal shedding at both doses were measured. Based on PRISMA criteria, nine clinical study articles were selected, and data were analysed for OPV seroconversion, nOPV stool shedding, mOPV stool shedding, and adverse event claims, including claimed and unclaimed adverse events.

Participants treated with the first dose of mOPV showed slightly less fecal shedding than those treated with the second dose, although

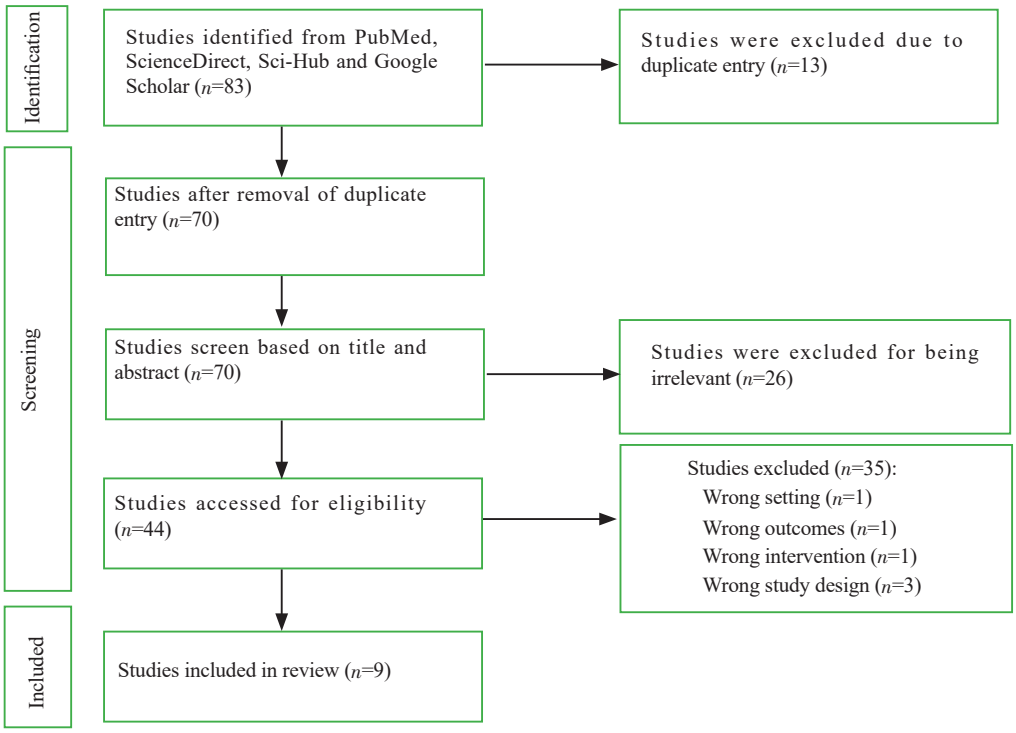

Figure 1. Selected articles for inclusion.

Table 1. Summary of studies included in the meta-analysis for studying viral shedding and seroconversion.

No.	Study	Region	Study design	Intervention	Individuals enrolled for study	Results	Reference
1	Brickley FB, *et al*; 2018	USA	Randomised controlled trail	OPV+IPV at 8, 16 and 24 weeks; mOPV2 at 28 weeks	*n*=152	Positive viral shedding	[27]
2	De coster, *et al*; 2021	Belgium	Randomised controlled trail	Precisely immunized with IPV, OPV or both were tested with mOPV2	*n*=350 Age 18-50	Both novel OPV2 candidates appeared to be as safe, well tolerated, and immunogenic as monovalent OPV2, with similar profiles of viral shedding	[15]
3	Ferreyra-Reyes L, *et al*; 2017	Mexico	Randomised controlled trail	IPV+OPV Immunized population were observed for percent VDPV transmission	*n*=216 Children: 72; Adults: 144	Positive viral shedding was observed in population immunized with IPV + OPV	[28]
4	Gast C, *et al*; 2021	USA	Randomised trail	Control: mOPV2 study: nOPV2/IPV or bOPV	*n*=684 Healthy infants with more than 6 weeks of age	nOPV vaccinated individual observed less viral shedding	[29]
5	Van Damme, *et al*; 2019	Belgium	Randomised trail	nOPV IPV	*n*=30 18-50 years	Positive effect nOPV showed less faecal shedding	[10]
6	Zaman K, e*t al*; 2023	Bangladesh	Randomised controlled trail	nOPV at birth and 4 weeks	*n*=334 Newborn infants	The nOPV2 group showed a lower positivity rate for type 1 virus after the first dose of the bivalent OPV was administered	[14]
7	Aziz AB, *et al*; 2022	Bangladesh	Randomised control trail	For children who have not received IPV, 1 dose was administered, followed by the second dose after 2 months	*n*=380 Children (9-13 months)	Higher than expected seroconversion	[7]
8	Saleem AF, *et al*; 2015	Pakistan	Randomised controlled trail	bOPV+IPV	*n*=3 296	No significant results were obtained	[17]
9	Laassri M, *et al*; 2005	USA	Randomised trail	OPV+IPV	*n*=281 Infants	IPV showed negative viral shedding while OPV showed positive	[30]

OPV: Oral polio vaccine; mOPV: Monovalent oral polio vaccine; nOPV: Novel oral polio vaccine; bOPV: Bivalent oral polio vaccine; IPV: Inactivated polio vaccine.

the difference between the two was not statistically significant (*OR*: 1.02, 95%*CI*: 0.51-2.03, *P*=0.47, I^2= 59.97%) (Figure 2A). However, participants who received nOPV showed decrease in fecal virus shedding after dose 1 compared with dose 2 and the difference between the two was found to be statistically significant (*OR*: 2.95, 95% *CI*: 1.39-6.25, *P*=0.00, I^2= 87.16%) (Figure 2B).

Sero-conversion rates in mOPV-treated participants did not differ between the two doses (O*R*: 1.10, 95%*CI*: 0.60-2.01, *P*=0.35, I^2= 53.27%) (Figure 2C), meaning that the difference between the two was not statistically significant. Participants treated with nOPV had a higher sero-conversion rate and the data obtained was statistically significant (*OR*: 0.07, 95%*CI*: 0.01-0.67, *P*=0.01, I^2 = 93.42%) (Figure 2D). No statistical significance is reported (solicited). The adverse events was observed between the two doses (*OR*: 1.87, 95%*CI*: 0.15-22.66, *P*=0.14; I^2= 70.33%) (Figure 2E), whereas statistical significance in unreported (unsolicited) adverse events was observed between the two doses (*OR*: 1.05, 95%*CI*: 0.98-1.13, *P*=0.001, I^2 = 0%) (Figure 2F).

Asymmetry in funnel plots can indicate the presence of publication bias. However, in this meta-analysis, we found no evidence of publication bias. The funnel plots displayed symmetrical patterns, suggesting an absence of bias. This finding is corroborated by both Egger's intercept test and Begg and Mazumdar's correlation test, which both produced *P*-values greater than 0.1. Typically, *P*-values less than 0.1 would suggest significant asymmetry and potential publication bias, but in this case, the higher *P*-values indicate no significant asymmetry. Therefore, the statistical analyses confirm the absence of publication bias in our study (Figure 3).

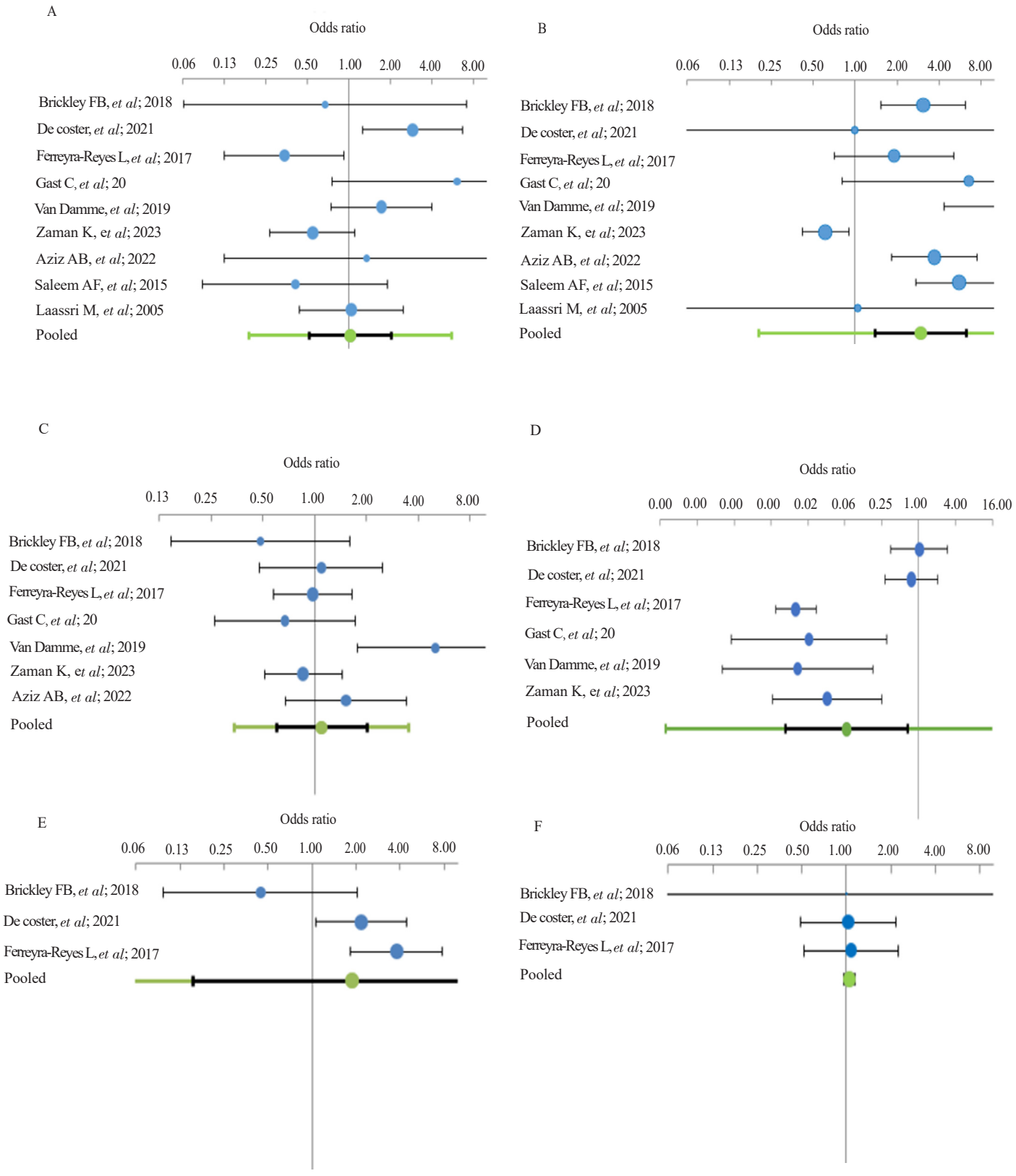

Figure 2. Comparative analysis of fecal shedding, seroconversion, and adverse events associated with OPV and nOPV. (1) Figure 2A: Tabular representation and forest plot of mOPV fecal shedding; (2) Figure 2B: Tabular representation and forest plot of nOPV fecal shedding; (3) Figure 2C: Tabular representation and forest plot of OPV seroconversion; (4) Figure 2D: Tabular representation and forest plot of nOPV seroconversion; (5) Figure 2E: Tabular representation and forest plot of adverse events (solicited); (6) Figure 2F: Tabular representation and forest plot of adverse events (un-solicited). The green dots at the bottom of the graph represent the pooled analyses from all available studies.

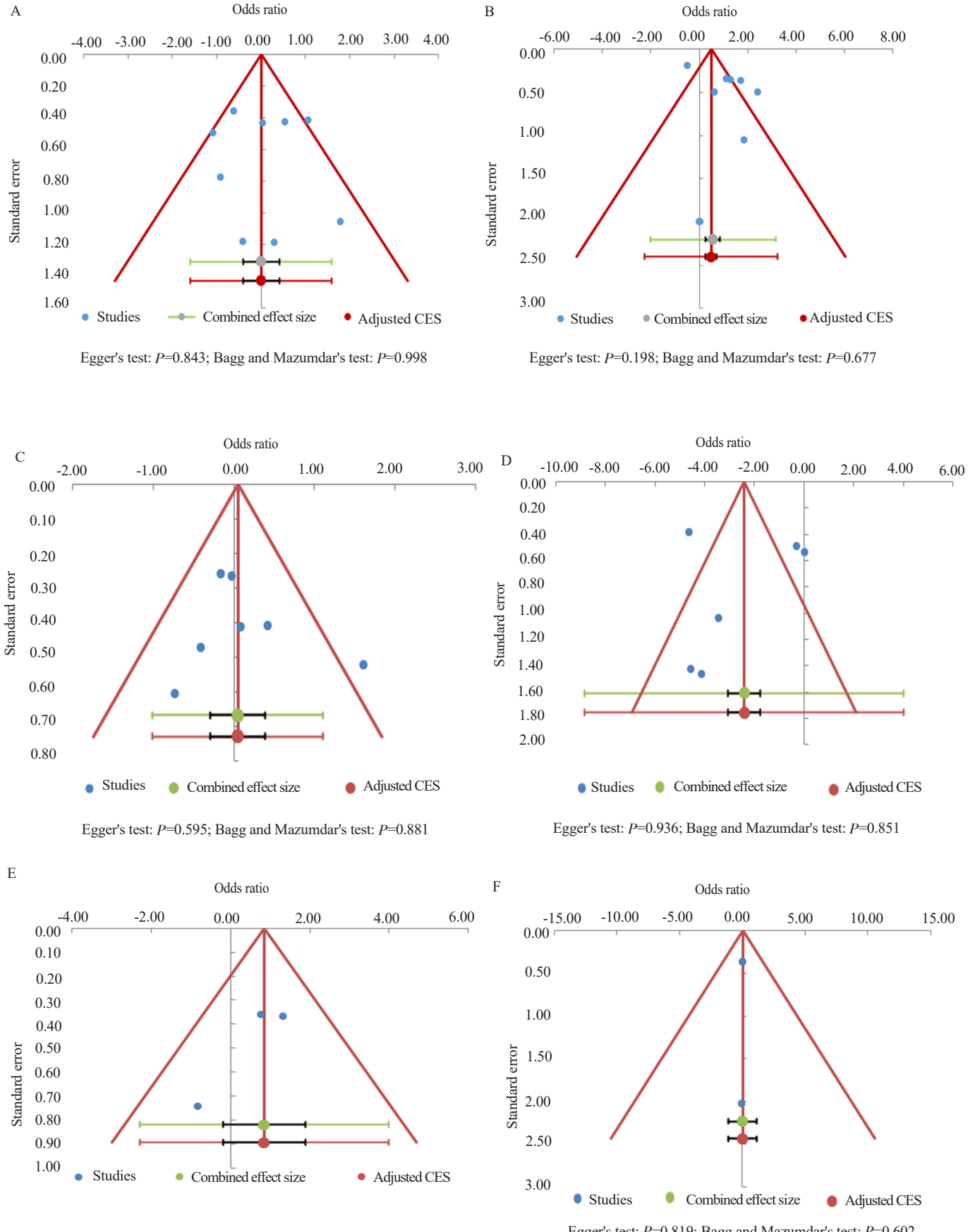

Figure 3. Funnel plot with pseudo 95% confidence limits. Adjusted CES: Adjusted combined effect size. $P<0.1$ indicate presence of publication bias.

4. Discussion

This meta-analysis demonstrated that patients receiving nOPV were likely to have a reduced shedding outcome compared to those who did not receive it[29]. The nOPV vaccine is a modified form of type 2 monovalent OPV (mOPV2), which clinical trials have demonstrated offers equivalent resistance against poliovirus while being more genetically stable and less likely to be related to the onset of VDPV in low immunity situations[10]. Attenuated (weakened) variants of the live poliovirus are present in oral polio vaccinations (OPV), which are used to prevent and control polio epidemics[9]. Through the production of antibodies, the vaccination virus induces an immune response against paralytic poliomyelitis. It also reproduces in the human GI tract and is predominantly eliminated by stools in communities[31]. In most cases, this viral replication and excretion in the community is beneficial because it allows for passive immunization against the poliovirus, as the vaccine virus induces mucosal immunity at the site of viral replication and is shed for several weeks[4, 29].

People receiving nOPV showed a statistically significant reduction in virus fecal shedding compared to those receiving other vaccines[29]. Participants who got the nOPV showed less fecal shedding than those who received the mOPV, according to a comparison of the two vaccines[29]. As a result, nOPV was clinically superior over mOPV. The sero-conversion rate between the two dosages of mOPV was not significantly correlated, indicating the clinical importance of mOPV is minimal. However, participants who received the nOPV had a greater rate of sero-conversion[32]. Thus, the therapeutic benefit of nOPV for sero-conversion was observed.

This meta-analysis provides evidence confirming the significant clinical benefit of nOPV, suggesting that nOPV should be routinely used for immunization by national programmes. The overall combined outcomes were found to be stable.

Additional data confirmed that one of the adverse events linked to VDPV was acute flaccid paralysis[9,33]. Clinically described as limb drooping, intense muscle discomfort, spasms, and loss of muscle reflexes, often on one side of the body. Fever, sore throat, headache, vomiting, and exhaustion were additional symptoms in addition to paralysis. When compared to other vaccines, the nOPV exhibited a relatively superior safety profile. The few adverse effects reported by nOPV make its safe in infants and young children[34].

Conflict of interest statement

The authors declare that there is no conflict of interest.

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This study received no extramural funding.

Data availability statement

The data supporting the findings of this study are available from the corresponding author upon request.

Authors' contributions

Yunus GM conducted the literature search, collected and analyzed the data, and drafted the manuscript. Taher KA, Anil DS, and Akarm KA contributed to the study design and provided feedback. Anis HS created the tables and figures and helped draft the manuscript. Shaikh A proposed the research problem, supervised the research process, including tool development and data analysis, and reviewed and approved the final manuscript. All authors reviewed and approved the final version of the manuscript.

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