

Efficacy of the Oral Cholera Vaccine Shanchol® in Preventing Cholera: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Background

Oral cholera vaccines (OCVs) have become a crucial part of global strategies for cholera prevention, working alongside water, sanitation, and hygiene (WASH) initiatives. However, estimates of vaccine efficacy can vary depending on the context. This systematic review and meta-analysis aimed to assess the protective efficacy of the killed whole-cell bivalent OCV, Shanchol®, against laboratory-confirmed cholera.

Methods

In accordance with PRISMA 2020 guidelines, a comprehensive search was conducted in PubMed, Scopus, the Cochrane Library, EMBASE, and ISI Web of Science for randomized controlled trials (RCTs) published up to February 2023. Eligible studies compared two doses of Shanchol® with a placebo or no vaccination in either endemic or epidemic regions. Data were pooled using a random-effects model (DerSimonian–Laird method), with vaccine efficacy (VE) calculated using the formula $VE = (1 - OR) \times 100$. The risk of bias was assessed using the Cochrane RoB 2 tool, and publication bias was examined through funnel plots.

Findings

Six RCTs conducted between 2011 and 2019 in India and Bangladesh met the inclusion criteria, involving a total of 627,982 participants (361,119 vaccinated and 266,863 controls). The pooled odds ratio was 0.41, translating to a vaccine efficacy of 59% (95% CI: 52%–65%; $p < 0.001$). Between-study heterogeneity was moderate ($I^2 = 40\%$, $p = 0.09$). All trials showed statistically significant protection in favor of vaccination. The risk of bias was generally low, with funnel-plot symmetry indicating no significant publication bias.

Conclusions

Two doses of Shanchol® provide substantial and consistent protection against cholera, reducing the incidence of the disease by approximately 59%. These findings support the World Health Organization's recommendation to use OCVs as a complement to WASH interventions for both outbreak response and ongoing endemic control. Expanding vaccine access, combined with sustained improvements in sanitation and surveillance, is essential for achieving the Global Roadmap to 2030 goal of reducing cholera deaths by 90%.

Introduction

Cholera is an acute diarrheal illness caused by the bacterium *Vibrio cholerae*, primarily spread through the consumption of contaminated water or food [1]. It continues to pose a significant global health threat, especially in low- and middle-income nations, where inadequate water and sanitation systems

contribute to frequent outbreaks, resulting in considerable illness and death [2]. The World Health Organization (WHO) estimates that from 2010 to 2020, cholera was responsible for 1.3 to 4.0 million cases and 21,000 to 143,000 deaths each year worldwide [3].

Alongside traditional control measures like improved water, sanitation, and hygiene (WASH), disease surveillance, and case management, oral cholera vaccines (OCVs) have become an essential component of cholera prevention and control initiatives [4]. Vaccination has proven to be one of the most effective strategies for lowering the risk of infection and managing outbreaks. Various types of OCVs are available, all of which have shown safety and effectiveness in both endemic and epidemic contexts [5]. Successful OCV campaigns have been carried out in countries such as Bangladesh, Haiti, and Yemen, significantly aiding in outbreak management and reducing disease transmission [6, 7].

Despite their demonstrated potential, uncertainties remain regarding the magnitude and consistency of OCV effectiveness across populations and epidemiological settings. Some studies report strong protective effects and reductions in cholera incidence following OCV campaigns, while others suggest modest or limited impact due to factors such as campaign timing, vaccine coverage, and population mobility [8, 9]. These mixed findings highlight the need for further evaluation of OCV performance in diverse contexts.

Historically, cholera vaccines were first introduced widely in the 1960s, consisting of injected whole-cell *V. cholerae* O1 preparations inactivated by heat or formalin [10]. However, due to low acceptance and suboptimal efficacy, these injectable vaccines were phased out in the 1970s. Since the 1980s, research and development have focused on oral formulations, leading to the availability of both killed and live attenuated OCVs, which have been tested extensively for immunogenicity, efficacy, and effectiveness [11].

Currently, three main OCV formulations are licensed and available: Dukoral® (WC/rBS), a monovalent killed whole-cell vaccine containing recombinant cholera toxin B subunit; Shanchol® (BivWC), a bivalent killed whole-cell vaccine containing *V. cholerae* O1 and O139; and mORCVAX®, which has an identical composition to Shanchol® but is produced in Vietnam using different methods [12, 13]. Dukoral® requires two doses and provides short-term protection, while Shanchol® and mORCVAX® can confer longer-lasting immunity with two doses given one to two weeks apart [14]. In addition, live attenuated single-dose vaccines are under development, along with several promising candidates in different stages of clinical evaluation [15].

Given the substantial global cholera burden and the growing use of OCVs in outbreak response and endemic control, a systematic review and meta-analysis of randomized controlled trials and controlled clinical trials is warranted. Such an analysis can provide comprehensive evidence on the efficacy of OCVs in reducing cholera incidence at both individual and population levels, thereby informing vaccination strategies and policy decisions aimed at achieving sustained cholera control.

Methods

Study Design and Registration

This study was conducted as a systematic review and meta-analysis of randomized controlled trials (RCTs) to evaluate the protective efficacy of oral cholera vaccines (OCVs). The protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO, registration number CRD42022351144). We adhered to the guidelines set forth by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) [16], and followed the methodological recommendations outlined in the Cochrane Handbook for Systematic Reviews of Interventions [17].

Literature Search Strategy

A comprehensive search strategy was developed with the help of a subject librarian. We systematically searched five electronic databases: PubMed (last searched on December 15, 2021), Scopus and the Cochrane Library (searched on January 30, 2022), EMBASE, and ISI Web of Science (searched on February 3, 2022).

The search utilized both controlled vocabulary (such as MeSH terms) and free-text terms, focusing on three main concepts:

- Population: “cholera prevalence” OR “cholera incidence”
- Intervention: “oral cholera vaccine” OR “killed oral cholera vaccine” OR “live oral cholera vaccine”
- Outcomes: “efficacy,” “effectiveness,” OR “protection”

Detailed search strategies for each database can be found in *Supplementary File*. We did not impose any restrictions on the year of publication, but only studies published in English were included.

Eligibility Criteria

Studies were deemed eligible if they met the following **inclusion criteria**:

- Design: Randomized controlled trials.
- Population: Children or adults in cholera-endemic or epidemic regions.
- Intervention: At least one dose of any licensed oral cholera vaccine (e.g., Shanchol®, Dukoral®, or mORCVAX®).
- Comparator: Placebo or an unvaccinated control group.
- Outcomes: Laboratory-confirmed cholera cases, cholera incidence or prevalence, and/or reported vaccine efficacy or effectiveness.

The **exclusion criteria** were as follows: **(i)** observational or modeling studies, **(ii)** trials involving parenteral cholera vaccines, **(iii)** studies lacking extractable outcome data, and **(iv)** publications not in English.

Study Selection

Three reviewers (LM, MS, and MJ) independently screened all titles and abstracts, followed by a review of the full texts of potentially relevant articles. Any disagreements were resolved through discussion or by consulting a fourth and fifth reviewers (SN and LMM). The study selection process was recorded using a PRISMA flow diagram.

Data Extraction

Data extraction was carried out independently by two reviewers using a standardized form. The information extracted included:

- Study characteristics: Author, year, and country.
- Vaccine type and formulation.
- Number of doses and dosing interval.
- Sample sizes for both intervention and control groups.
- Number of laboratory-confirmed cholera cases in each group.
- Reported vaccine efficacy/effectiveness and duration of follow-up.
- Adverse events, when available.

Any discrepancies were resolved through consensus.

Risk of Bias Assessment

The methodological quality of the included randomized controlled trials (RCTs) was evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool [18]. This tool assesses five areas: the randomization process, deviations from the intended interventions, missing outcome data, measurement of outcomes, and selective reporting. The results were summarized in both tabular and graphical formats (see *Supplementary File*).

Data Synthesis and Statistical Analysis

Meta-analysis was performed using Stata version 17. For dichotomous outcomes, we analyzed odds ratios (ORs) with 95% confidence intervals (CIs). Vaccine efficacy (VE) was calculated from the pooled ORs using the following formula [19]:

$$VE=(1 - OR) \times 100$$

We employed a random-effects model (DerSimonian and Laird method) to account for variability between studies [20]. Heterogeneity was assessed using the I^2 statistic, with values of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively [18]. Publication bias was visually assessed through funnel plots (see *Supplementary File*).

Results

Study Selection

A total of 2,276 records were found through searches in PubMed, Scopus, the Cochrane Library, EMBASE, and ISI Web of Science. These records underwent screening and eligibility assessment according to the PRISMA 2020 guidelines. After removing duplicates and ineligible entries, 187 full-text articles were reviewed. Out of these, 181 studies were excluded for various reasons, including unsuitable study designs (like observational or non-randomized controlled trials), the type of vaccine used (non-oral cholera vaccines), or a lack of sufficient outcome data. In the end, six randomized controlled trials met all the inclusion criteria and were included in the final analysis (see Fig. 1).

Study Characteristics

The six eligible randomized controlled trials (RCTs) were conducted between 2011 and 2019 in regions of India and Bangladesh affected by cholera outbreaks. These studies—by Fong Y et al. (2018) [21], Im J et al. (2019) [22], M Ali et al. (2019) [23], Sur D et al. (2011) [24], Ali MS et al. (2013) [25], and Bhattacharya et al. (2013) [26]—all focused on evaluating two doses of the killed whole-cell bivalent oral cholera vaccine, Shanchol®. Table 1 presents a summary of the main features of these studies.

In total, the trials involved 627,982 participants, with 361,119 receiving the vaccine and 266,863 in control or placebo groups. The time between doses varied from one to two weeks. Vaccine efficacy across the trials ranged from 51% to 67%, demonstrating consistent moderate protection among different study populations and epidemiological settings. Importantly, despite differences in the populations and contexts—whether endemic or epidemic—the vaccine consistently provided a protective benefit, indicating its efficacy in various cholera-prone areas.

Table 1
Characteristics of Randomized Controlled Trials Included in the Meta-Analysis

Criteria	Fong Y et al	Im J et al	M Ali et al	Sur D et al	Ali MS et al	Bhattacharya et al
Year	2018	2019	2019	2011	2013	2013
Country	India	Bangladesh	Bangladesh	India	India	India
Vaccine	Shanchol	Shanchol	Shanchol	Shanchol	Shanchol	Shanchol
Dose	2	2	2	2	2	2
No. of Vaccines	31619	25416	187214	31932	52515	32866
No. of Controls	34 596	25354	80056	34 968	55834	34968
V. Efficacy	64%	51%	58%	67%	66%	65%

Pooled Vaccine Efficacy

The random-effects meta-analysis revealed a pooled odds ratio (OR) of 0.41, which translates to a vaccine efficacy (VE) of 59%. This is calculated as $VE = (1 - OR) \times 100 = (1 - 0.41) \times 100$. The confidence interval for this finding is 95%, ranging from 52% to 65%, with a p-value of less than 0.001.

Figure 2 shows a forest plot that illustrates the point estimates and 95% confidence intervals for each study, along with the overall pooled effect. All studies indicated a positive impact of vaccination, and the overlapping confidence intervals further confirm the consistent protective effect of Shanchol®.

The heterogeneity between the studies was moderate ($I^2 = 40\%$, $p = 0.09$), which supports the appropriateness of using a random-effects model to account for the variability among the trials. The forest plot demonstrates that two doses of Shanchol® significantly lower the risk of laboratory-confirmed cholera infection in both endemic and epidemic environments, indicating strong protection from the vaccine and a low level of heterogeneity across the studies.

Risk of Bias Assessment

The methodological quality of the included trials was generally high. Using the Cochrane Risk of Bias 2 tool, most studies were assessed as having a low risk in the areas of randomization, outcome measurement, and selective reporting. There were only minor concerns about missing outcome data (see *Supplementary Fig. 1*). Overall, the quality of the studies was deemed adequate for conducting a meta-analysis.

Publication Bias

A visual inspection of the funnel plot indicated that it was approximately symmetrical, which suggests that there is no significant publication bias (see *Supplementary Fig. 2*). The distribution of study estimates was well-balanced between smaller and larger trials, reinforcing the reliability of the pooled results.

Summary of Findings

In summary, across six high-quality randomized controlled trials conducted in India and Bangladesh, two doses of Shanchol® demonstrated a pooled vaccine efficacy of 59% (95% CI: 52%–65%) against laboratory-confirmed cholera. The consistent findings from large sample sizes, along with moderate heterogeneity and the absence of publication bias, provide strong evidence that oral cholera vaccines are an effective part of the cholera control strategies recommended by the World Health Organization.

Discussion

This meta-analysis brought together data from six randomized controlled trials conducted in India and Bangladesh to assess the protective efficacy of the killed whole-cell bivalent oral cholera vaccine, Shanchol®. Despite variations in population and environmental factors, the overall protective effect of the vaccine remained consistent and strong.

The findings from Fong et al. (2018) in India indicated an efficacy of 64% over five years. Im et al. (2019) reported 51% efficacy in Bangladesh when the vaccine was used for culture-negative cholera cases. M Ali et al. (2019) found 58% efficacy in a large trial in Bangladesh, which also suggested evidence of herd protection. Sur et al. (2011) observed 67% efficacy in India under endemic conditions. Additionally, both Ali et al. (2013) and Bhattacharya et al. (2013) conducted in Kolkata, India, reported efficacies of 66% and 65%, respectively, with protection lasting for at least three years [21, 22, 23, 24, 25, 26]. Together, these results confirm that two doses of Shanchol® provide reliable and consistent protection against *Vibrio cholerae* infection.

Our pooled estimate closely matches previous global reviews. Bi Q et al. (2017) [27] reported an overall efficacy of 58% for killed whole-cell oral cholera vaccines, and Song KR et al. (2021) [28] found similar protection across endemic settings. The alignment between these earlier studies and our present analysis confirms the robustness of Shanchol® efficacy. Immunological studies have shown that repeated oral administration of killed whole-cell vaccines induces durable mucosal and systemic immune responses [5, 14], which explains the sustained protection observed in the field.

The variation in observed efficacy is likely due to differences in host immunity, age distribution, vaccine coverage, and the timing of outbreaks. The trials conducted in Bangladesh included younger populations who had prior exposure to cholera [22, 23], while the trials in India recruited broader community groups [21, 24, 25, 26]. Despite these contextual variations, all studies demonstrated statistically significant protection, confirming that Shanchol® is effective across various epidemiological conditions.

These findings support the World Health Organization (WHO) recommendation to use oral cholera vaccines as a complement to standard prevention and control strategies [12]. When paired with improvements in water, sanitation, and hygiene (WASH), alongside comprehensive surveillance [4, 8, 9], oral cholera vaccines significantly lower cholera transmission rates and mortality. Long-term follow-up from the Kolkata trials showed that protection lasts for three years or more [21, 26], underscoring the programmatic value of the two-dose regimen for both preventive and reactive vaccination efforts.

Limitations

This meta-analysis has several limitations. First, all six trials were conducted in South Asia, which may limit the applicability of the findings to other regions, such as sub-Saharan Africa or Latin America, where *Vibrio cholerae* strains and environmental conditions vary. Second, the relatively small number of available randomized controlled trials makes it difficult to detect subtle publication bias, even though the funnel plot appeared symmetrical. Third, data limitations hindered subgroup analyses by factors such as age, vaccine interval, or baseline immunity. Additionally, variations in follow-up duration across the studies may have affected the pooled efficacy estimate. Future research should prioritize assessing vaccine performance in different geographic areas, exploring single-dose and booster strategies, and conducting long-term implementation studies to evaluate real-world effectiveness in programmatic settings.

Conclusion

This meta-analysis of six randomized controlled trials confirms that two doses of Shanchol® offer significant and consistent protection against cholera, with a pooled efficacy of 59% (95% CI: 52%–65%). The consistent direction of effect, moderate heterogeneity, and lack of publication bias provide strong support for Shanchol® as an effective vaccine for both controlling endemic cholera and responding to epidemics. These findings bolster WHO recommendations and underscore the importance of incorporating oral cholera vaccination alongside sustainable water, sanitation, and hygiene (WASH) initiatives. Expanding vaccine access, along with ongoing improvements in sanitation and surveillance, is crucial for achieving the Global Roadmap to 2030 goal of reducing cholera deaths by 90% worldwide.

Declarations

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Authors' Contributions

Luay M. Mohammed (LM) conceived and designed the study, led data analysis, and drafted the manuscript. Mustafa A. Suraifi (MS) contributed to study selection, data extraction, and critical revision. Mohammad A. Jalal (MJ) participated in data interpretation and manuscript editing. Seyed Saeed Hashemi Nazari (SN) and Lezan Medhat Mohammed (LMM) supervised the research, verified statistical methodology, and provided overall guidance. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability

All data generated or analyzed in this study are included in this published article and its supplementary material. Additional details are available from the corresponding author upon reasonable request.

Use of Generative AI

Portions of the manuscript, including language refinement and structural formatting, were assisted by the Poe (Quora, 2025) system under the direction and full verification of the authors. All scientific content, data interpretation, and final conclusions were developed and validated by the authors.

Declarations and Competing Interests

The authors declare no competing interests and no financial or personal relationships that could inappropriately influence the work reported in this paper.

Ethics Approval and Consent to Participate

Not applicable. This study is a systematic review and meta-analysis based on previously published data and does not involve human participants or primary data collection.

Consent for Publication

Not applicable.

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Figures

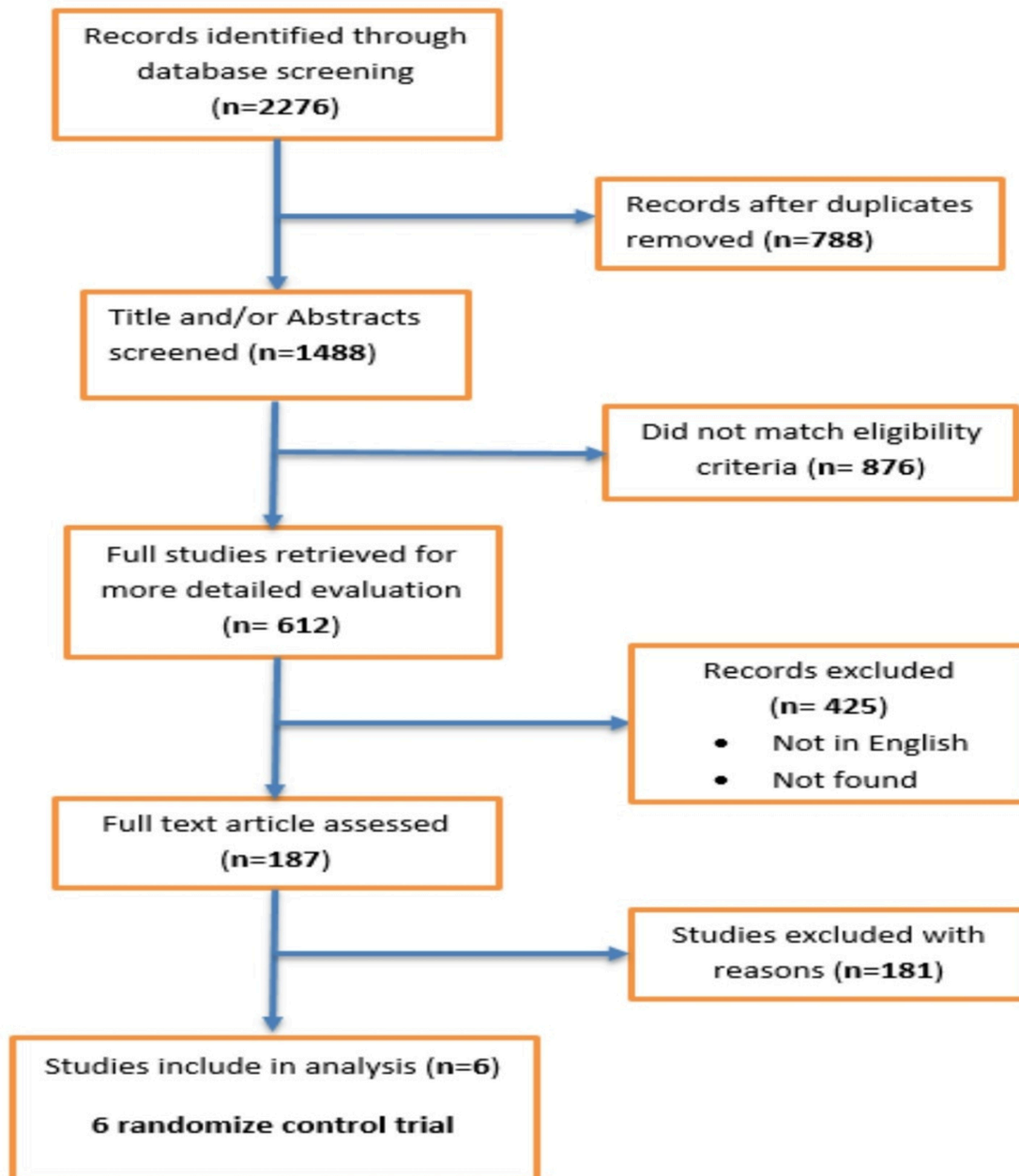


Figure 1

PRISMA Flow Diagram of Study Selection (*The diagram illustrates the number of studies retrieved, screened, excluded, and finally included. It demonstrates the rigorous filtering process that resulted in six high-quality RCTs forming the evidence base for this review*)

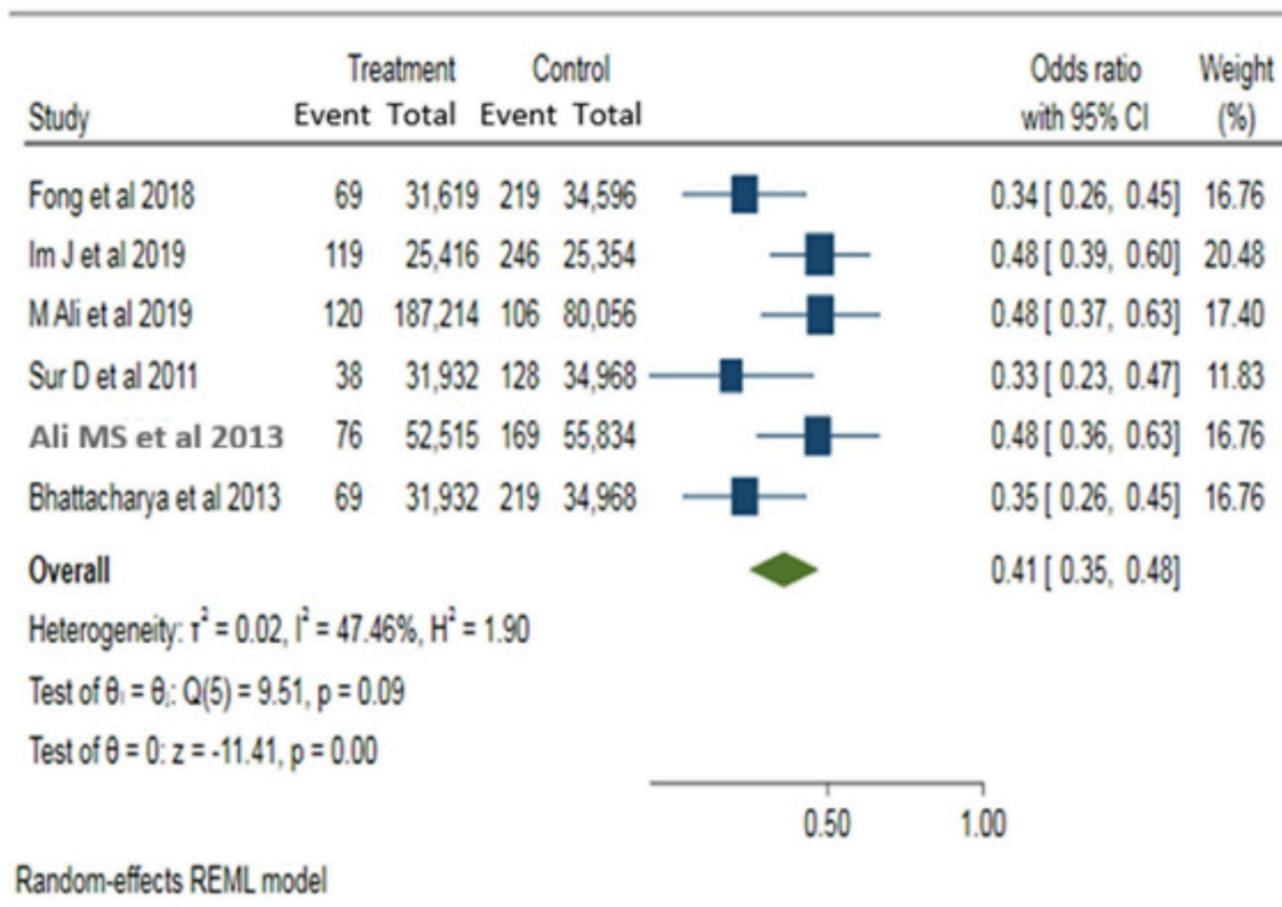


Figure 2

Forest Plot of Oral Cholera Vaccine Efficacy (Two Doses of Shanchol®)

Supplementary Files

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