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Efficacy of single-dose HPV vaccine over no vaccination and standard multiple dose regimen: a systematic review and meta-analysis of available evidence

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Abstract

Background: The logistical and financial challenges posed by the current multi-dose Human Papillomavirus (HPV) vaccines in countries with limited resources, result in low vaccine coverage, and thus are big hurdles against effective prevention for cervical cancer. This study compared the efficacy of a solitary dose of HPV vaccine regimen with standard multi-doses.

Methods: The PRISMA guidelines were followed. A thorough search was conducted till January 10, 2024, to identify studies investigating the HPV vaccine's efficacy with single versus multiple doses or no dose. For the meta-analysis, a random-effects model was used, considering heterogeneity with I^2 statistics. Included studies were also assessed for quality using standard tools.

Results: Three observational studies were included with two randomized controlled trials. The meta-analysis comparing individuals given a single dose of the HPV vaccine to those with no dose, revealed an insignificant RR (risk ratio) of 2.11 (95%CI [0.34; 12.87]) with high heterogeneity, which on adjusting for outlier, became significantly better (RR of 1.09 (95%CI [1.04; 1.14]); I^2 = 33.6%). The comparison of single-dose with two-dose regimens showed no significant difference, while that with three-dose regimens revealed an RR of 2.21 (95%CI [0.07; 66.28]), with I^2 = 95%. However, a leave-one-out analysis with two- and three-doses, indicated significantly less protection with single dose, RR of 0.81 (95%CI [0.67;0.98]) and 0.78 (95% CI [0.77; 0.79]), respectively. The included studies and trials had moderate to high quality.

Conclusion: A single-dose HPV vaccine regimen could offer a potential interim solution in preventing incident HPV infection, especially in resource-limited settings (like LMICs) where simplifying vaccination logistics and reducing costs could significantly enhance vaccine accessibility and coverage. However, more evidence is needed to confirm these results and assess the long-term effectiveness of the single-dose regimen.

Keywords: *HPV; vaccine efficacy; cervical cancer; single dose; multiple doses; systematic review; meta-analysis*

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Evidence in Context

• A single HPV vaccine dose effectively protects against key HPV types. • Single-dose vaccination can reduce costs and improve adherence in under-developed countries. • WHO-SAGE supports single-dose efficacy, but further studies are needed for specific groups. • High study variability calls for more research on long-term efficacy.

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Introduction

Cancer burden is on a consistent rise and cervical cancer is one of the commonest worldwide. More than 600 million new cases of Cervical cancer are detected every year, leading to large medical, non-medical expenses and losses in productivity [1,2].

The incidence of cervical cancer is notably higher in low- and middle-income countries (LMICs) [3,4]. But, a formidable coverage with Human Papilloma Virus (HPV) vaccination among girls along with a double screening of women aged 35 and 45 years with adequate treatment facilities is highly conducive to the elimination of cervical cancer [3,5].

There are currently three licensed vaccines approved for prophylactic use against HPV, viz., bivalent, quadrivalent and non-valent vaccines [6]. Almost 90% of new HPV related cancers can be prevented with successful vaccination [7]. However, HPV vaccines are currently recommended as multiple doses [8]. This presents a significant problem to the public health systems of the LMICs, which are often inadequately organized, improperly funded and insufficiently staffed [9-11]. The high costs associated with the production or procurement of HPV vaccines inhibit two-thirds of LMICs from implementing mass HPV vaccination as a part of their national programs [12,13]. According to 2019 estimates, barely 15% of people worldwide received the HPV vaccine [14,15]. These nations will be further impacted by the enormous supply and demand imbalance as the world's need for the vaccine is anticipated to increase to more than 100 million doses annually by 2030 [16,17].

Though the antibody levels specific to HPV types are notably lower following a single dose compared to three doses, the 'Strategic Advisory Group of Experts on Immunization' (SAGE) of WHO has noted that a solitary dose of the HPV vaccine still offers effective and long-lasting protection against HPV, similar to the protection provided by 2-dose schedules [18-20]. A shift from the multi-dose regimen to a single-dose schedule would mean a significant decline in associated costs and increased coverage. Single-dose regimens also improve the general effectiveness of vaccination programs by decreasing missed opportunities for people to acquire protection and increasing vaccine acceptance through perceived ease of use [21,22]. Additionally, logistical concerns are better managed. These could prove to be valuable in the LMICs.

In this article, we systematically review and meta-analysis existing evidence on vaccine efficacy (VE) of HPV vaccines, following a single-dose schedule and comparing its outcome with multi-dose regimens. We believe this effort will generate strong enough evidence that will help in developing informed policy decisions on HPV and cervical cancer prevention.

Methods

Overview

This review, adheres to PRISMA guidelines (**Table S1**) [23] and registered in PROSPERO (ID: CRD42023494907), employed a comprehensive approach to gather and analyze literature on HPV vaccines. Utilizing multiple databases, the research spanned the complete history of each database until January 10, 2024. The Nested Knowledge platform a platform for conducting systematic reviews played a crucial role in managing the data. This included the removal of duplicate entries and the systematic screening of studies. The process of data extraction was meticulously carried out, with key information from each selected article being independently reviewed by two researchers to ensure accuracy and reliability. The review's robustness is further exemplified by its detailed statistical analysis using R software. The analysis involved a meta-analysis to determine the vaccine's effectiveness, which utilized a random-effects model, sensitivity analysis, and evaluated publication bias through both the Doi plot and LFK index. The 'Cochrane Risk of Bias tool-2' for randomized trials and the 'Newcastle-Ottawa Scale' for observational studies were used for quality assessment.

Search strategy and selection criteria

To identify relevant articles and ensure a thorough review, two reviewers independently developed search strategies for multiple databases, including 'PubMed', 'Scopus', 'Web of Science', 'EMBASE', and 'Cochrane' library by using various keywords and MeSH terms related to HPV vaccine, children, adolescents, young adults, and infection incidence. The search strategy is given in **Table S2**. The literature search spanned from the inception of each database until January 10, 2024. The initial search was conducted on July 25, 2023, and subsequently re-run on January 10, 2024. The retrieved studies were added to Nested Knowledge to remove duplicates. The remaining studies were screened by two independent reviewers through a two-phase screening process, which included initial title and abstract screening, followed by screening for full-text, adhering to predefined eligibility criteria (**Table S3**).

Data extraction

The data extraction process was carried out on the Nested Knowledge platform. This involved tagging relevant information in each selected article, which was then compiled for meta-extraction. Key information extracted included the author names, publication year, design of the study, geographical location, participant demographics, type of HPV vaccine, number of doses, outcomes measured, and significant findings. To ensure accuracy and consistency, each article was reviewed by two independent researchers. In case of discrepancies, they were sorted out through discussion, or a third reviewer was consulted.

Statistical analysis

R software, v 4.3 was used for statistical analysis [24]. A meta-analysis was done to assess the absence of HPV DNA in individuals after receiving single or multiple doses of the HPV vaccine. We pooled data on the number of vaccinated individuals and those diagnosed as negative for HPV DNA using a random-effects model. The forest plot shows the pooled results along with I2 statistics measuring the extent of variability attributable to heterogeneity [25,26]. It also incorporated a 95% prediction interval and 'tau-squared statistic' for insights into the variance among studies [27]. The leave-one-out method was used for sensitivity analysis, by omitting each study evaluated the impact of individual studies on the pooled results. To assess publication bias, Doi plot and LFK index were utilized. The LFK index quantitatively measures the asymmetry in the plot, where a score between -1 and +1 suggests no asymmetry, a score beyond -1 or +1 but not exceeding -2 or +2 suggests slight asymmetry and a score outside -2 or +2 indicates significant asymmetry. A symmetrical triangle in the Doi plot indicates no publication bias. A p-value> 0.05 indicated statistical significance.

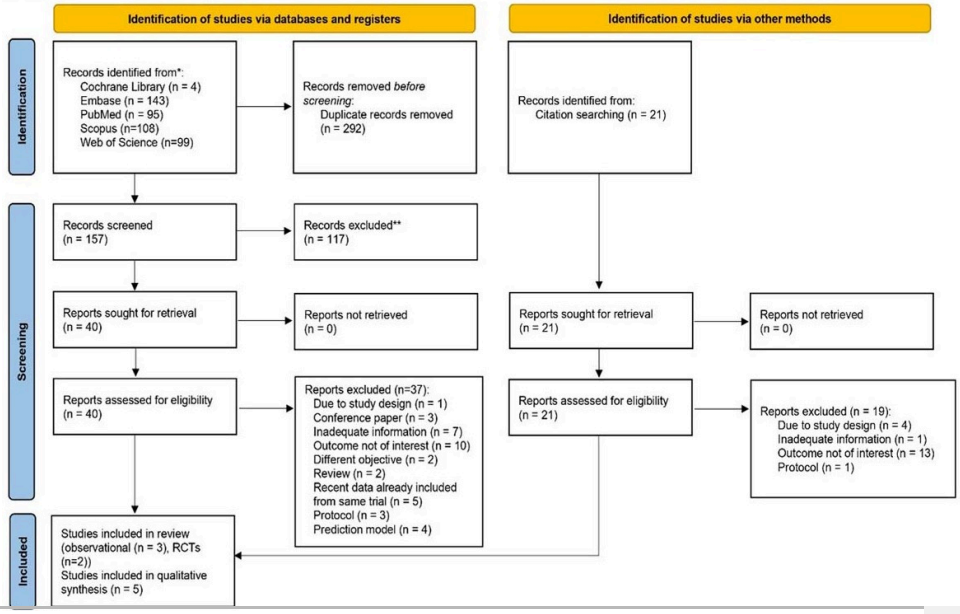
Quality Assessment

'Cochrane Risk of Bias tool-2' (RoB-2) assessed the quality of randomized controlled trials [28], whereas observational studies were evaluated using the 'Newcastle-Ottawa Scale' (NOS) [29]. This assessment helped determine the strength of the evidence provided by the studies and identify any potential biases that might affect the overall conclusions of the review.

Results

Literature search

Initially, 470 studies were identified across various databases, and after removing 292 duplicates, 157 studies remained for screening by title and abstract. Of the sixty-two that were suitable for complete text screening, only five studies satisfying the eligibility criteria, were included, as depicted in the PRISMA diagram (**Figure 1**), **Tables S4.** The quality of the studies was generally moderate to high.



Characteristics of the included studies

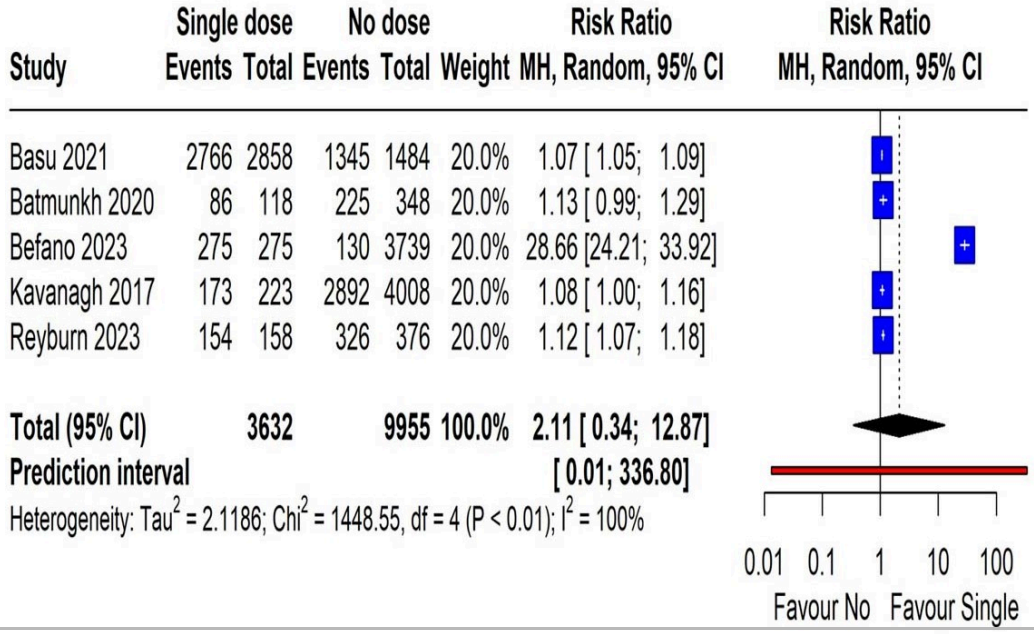
Table S1 provides a summary of the characteristics, including studies from India, Mongolia, Costa Rica, Scotland, and Fiji that focused on HPV vaccine effectiveness. These studies employed varied methodologies, including multicenter cluster-randomized trials, cohort studies, and cross-sectional studies. The sample sizes ranged from 118 to 17,729 participants. The studies examined both Quadrivalent and Bivalent HPV vaccines across different populations, including young girls, non-pregnant women, women at their first cervical screening, and pregnant women, with ages ranging from 10 to 23 years. The diagnostic methods used included Hybrid Capture II, Real-time PCR, HPV genotyping, and molecular methods. These studies provide a comprehensive view of HPV vaccine efficacy (VE) across different demographics and regions, employing a range of methodologies and yielding data of generally high quality.

Table 1. Summary characteristics of included studies.

Study	Age	Country	Type of vaccine	Diagnostic Method	Vaccinated group	Unvaccinated group
Basu 2021 (3)	10-18 years	India	Quadrivalent HPV vaccine	Hybrid Capture II	17,729	5172
Batmunkh 2020 (41)	20.4 (mean)	Mongolia	Quadrivalent HPV vaccine	Real time PCR	118	357
Befano 2023 (42)	NA	Costa Rica	Bivalent vaccine	NA	3727	3739
Kavanagh 2017 (33)	20-21 years	Scotland	Bivalent vaccine	HPV genotyping	446	4008
Reyburn 2023 (32)	15-23 years	Fiji	Quadrivalent HPV vaccine	Molecular methods	446	376

Meta-analysis

Comparing the reduced HPV detection rates in individuals who were administered one dose of the HPV vaccine against those who received no dose or multiple doses of the vaccine.

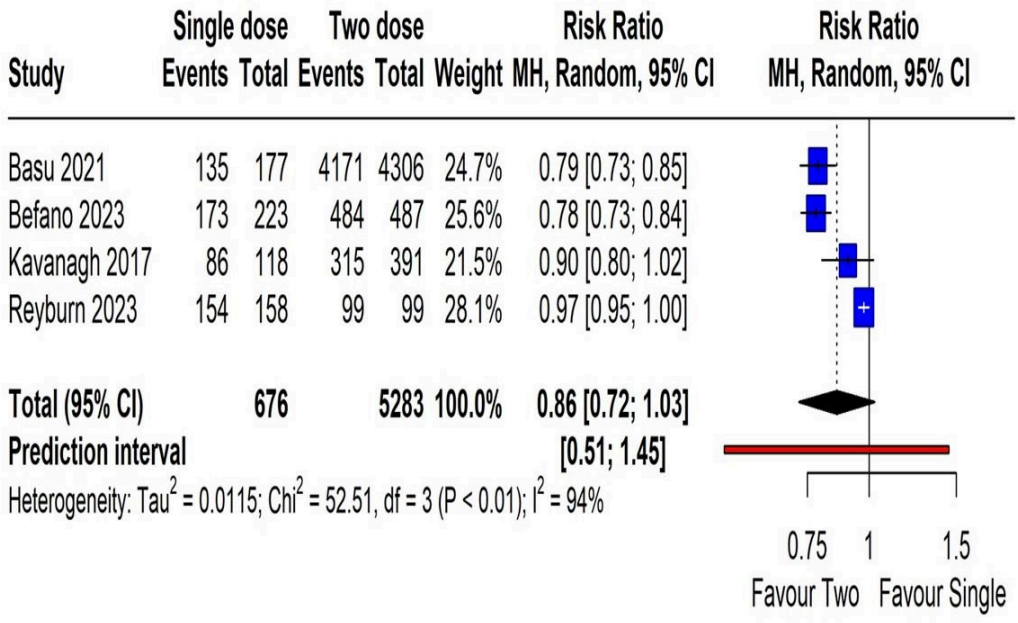


Single dose versus no dose

In total, 3,632 individuals received a single HPV vaccine dose, and 9,955 received no dose. The random effects model found an RR of 2.11 (95% CI [0.34; 12.87]), which was not statistically significant (p = 0.31) (**Figure 2**). Moreover, there was high heterogeneity (I^2 = 99.7%) across the studies. After removing an outlier study, "Befano 2023," the heterogeneity decreased significantly (I^2 = 33.6%), and the RR adjusted to 1.09 (95% CI [1.04; 1.14]), which was significant (p = 0.008) (**Figure S1**). This suggests that, without the outlier, receiving no vaccine may have a modestly increased risk of HPV DNA presence in comparison with a solitary dose of HPV vaccine.

Single dose vs two doses

Figure 3 Forest plot showing the comparison of a one dose to two doses; 676 individuals received a single dose, while 5,283 received two doses. The pooled RR was 0.86 (95% CI [0.72; 1.03]), which indicate a non-significant difference between the two regimens (p = 0.07). The analysis showed high heterogeneity (I^2 = 94.3%). A significant difference in RR was found in the leave-on-out analysis (**Figure S2**).



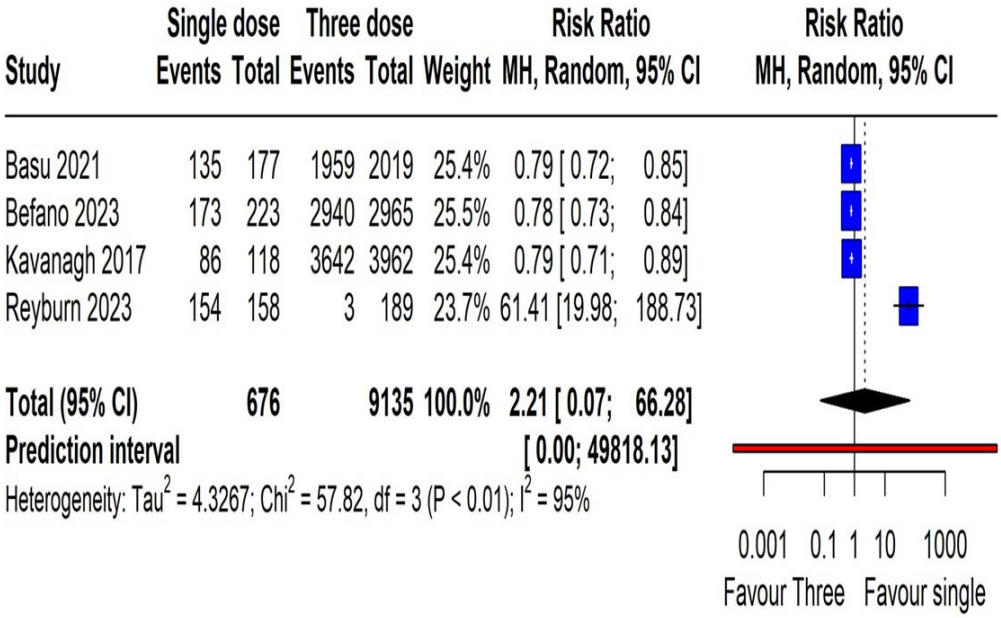
Single dose vs three doses

Figure 4 Forest plot comparing 676 individuals who received a single dose with 9,135 individuals who received three doses of the HPV vaccine. The pooled RR with random effect model was 2.21(95% CI [0.07-66.28]), indicating no statistically significant variance in HPV DNA presence between the two groups (p-value of 0.51). The high heterogeneity (I^2 = 95%) suggests variability across the included studies. The leave-one-out analysis revealed that by omitting a study Reyburn 2023, a significant difference was observed in the overall pooled RR of 0.78 (95% CI [0.77;0.79]) (I^2=0) with a p-value (0.0002), indicating that there is a remarkable VE in reduction in the presence of HPV DNA with a three-dose regimen compared to a single dose (**Figure S3)**.

Publication bias

The Doi plots and LFK index values indicate the presence of publication bias in all analyses: 4.92 for single dose versus no dose, -4.85 for single dose vs two doses, and 4.92 for single dose versus three doses (**Figure S4**).

We have done the Quality assessment of the included Studies using the Modified Newcastle-Ottawa Scale. The assessment for RCTs encompasses bias arising from five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of outcome, and selection of reported results, with an overall bias rating provided. For cohort studies, the assessment focuses on selection, comparability, and outcome measures, with an overall risk rating. Each parameter is evaluated and scored to provide a comprehensive overview of the study's methodological quality **[Table S4].**



Discussion

This review revealed an RR of 2.1 when comparing a single-dose HPV vaccine regimen to no vaccination, which was not statistically significant. Similarly, no significant differences in VE were observed when comparing a single dose to two (RR of 0.86) or three doses (RR of 2.21). However, after removing an outlier in the analyses, a statistically significant RR of 1.09 for single versus no dose, showing one dose was protective than no doses. The efficacy of a single dose was found significantly inferior to multidose regimens (both two- and three-dose), as evidenced by the RR of 0.81 and 0.71 for single versus two and three doses, respectively. Notably, without the outlier, the single dose was not significantly inferior than the two and three doses. This implies that a solitary dose might offer protection better than a no-dose scenario. It is important to note that the insights primarily apply to average-risk individuals, not to immunocompromised individuals.

Supporting this evidence, a previous systematic review by Setiawan et al [30] emphasized the effectiveness of a one-dose of vaccine, especially when contrasted with multi-dose schedules. Notably, the review indicates that a solitary-dose could match the efficacy of multi-dose schedules, offering immunogenic protection for up to eight years and effectively preventing infections and pre-cancer incidences [30]. Further supporting the efficacy of a single-dose regimen, Reyburn et al [31] and Kavanagh et al [32] reported high vaccine effectiveness against HPV types 16 and 18, with observational studies showing reduced cervical dysplasia following single-dose schedules. Another study by Basu et al [3], involving more than 4000 adolescent girls demonstrated that solitary dose of the quadrivalent HPV vaccine was much effective against persistent HPV 16/18 infection, with protection lasting up to 10 years after vaccination [3]. This level of efficacy is in line with the criteria set by the IARC in 2013, which regards a single-dose vaccine as effective in preventing advanced cervical cancers, particularly those caused by HPV types 16 and 18 [33]. The durability of this protection is significant, as antibody levels in single-dose recipients surpass those from natural infection for a decade, likely due to efficient induction of long-lived plasma cells by the vaccine [34].

Focussing on the LMICs, where challenges such as budget constraints and adherence to multi-dose HPV vaccine schedules are prevalent [35]. The study's findings suggest that a single-dose regimen might offer a feasible, and cost-effective alternative, especially in regions struggling with these issues. The potential of a single-dose regimen to provide protection comparable to multiple doses could significantly impact global efforts to reduce the burden of HPV-related diseases [36] Addressing the cervical cancer burden globally, and especially in LMICs, necessitates practical solutions like single-dose HPV vaccination [37]. This approach could help overcome disparities

That exacerbate HPV infection and significantly contribute to the eradication of cervical cancer by potentially enhancing vaccine coverage. Moreover, the findings indicate that countries with limited resources might still achieve significant public health benefits by adopting a single-dose HPV vaccination strategy [38]. This could be a game-changer in the global fight against cervical cancer, making prevention more accessible and equitable, particularly in areas where the burden of HPV and cervical cancer is highest [39]. The WHO-SAGE has recommended that one-dose of the HPV vaccine offers robust protection against the virus responsible for cervical cancer, comparable to the efficacy of a 2-dose regimen [37]. Nonetheless, additional research is required to confirm that this lower dosage schedule is effective for older populations and immunocompromised individuals [37]. Despite the current recommendation for a 3-dose series of the HPV vaccine, there is ongoing debate and evaluation of the potential for single or reduced-dose schedules, especially for specific age groups and demographic segments [36].

Nevertheless, it is vital to acknowledge the constraints of our review. The heterogeneity observed in comparing single-dose regimens with multiple-dose regimens suggests variability in study designs and populations, potentially affecting the generalizability of our findings. Additionally, the long-term efficacy of single-dose regimens is uncertain. The presence of publication bias in all comparative analyses, indicated by LFK index values, suggests an overrepresentation of studies with positive results, which could potentially the results. Due to a lack of suitable evidence, no studies from Africa and East Asia could be included – countries that have a significant burden of HPV infection and cervical cancer. As a measure of effectiveness, the presence or detection of the virus was considered, which alone does not guarantee HPV infection or malignancy. However, such a condition does increase the risk of both.

Conclusion

The potential effectiveness of a single-dose HPV vaccine regimen, which is comparable to multiple doses, is especially advantageous in settings with limited resources. This approach is relevant for LMICs, where constraints often impede the administration of multi-dose vaccines. Adopting a single-dose strategy could significantly enhance global HPV vaccination efforts by simplifying logistics, reducing costs, and potentially increasing vaccine coverage, at least till the time when a country can utilize available resources to implement a multi-dose schedule. However, further research and clinical trials are necessary to firmly establish this strategy.

Supporting information

None

Ethical Considerations

None

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Author contribution statement

Shibaji Gupta: Concept, design, the definition of intellectual content, literature search, data acquisition, manuscript preparation; **Srija Basu:** Concept, design, data analysis, manuscript editing and manuscript review; **Rudradeep Banerjee:** Definition of intellectual content, Literature search, Data acquisition, manuscript preparation

All authors attest they meet the ICMJE criteria for authorship and gave final approvalforsubmission.

Data availability statement

Data included in article/supp. material/referenced in article.

Additional information

No additional information is available for this paper.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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