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Association between the Implementation of Hepatitis B Vaccination Program and a Decrease in Disease Incidence: A Systematic Review

Cyprel Ijeh[1] and Faisal Ghafoor[2]*

[1]*Medical Director, Stemax Consult Healthcare Services Ltd, UK*

[2]*Strength and Conditioning Coach, Senior Physiotherapist, Sehat Medical Complex, The University of Lahore, Pakistan*

***Corresponding author:** Faisal Ghafoor, Strength and Conditioning Coach, Senior Physiotherapist, Sehat Medical Complex, The University of Lahore, Pakistan

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ABSTRACT

Introduction: Hepatitis B is a serious public health issue worldwide, which is caused by hepatitis B virus (HBV). It can result in life-threatening complications like liver cirrhosis and liver cancer and lead to death. Implementation of hepatitis B vaccination programs has sufficient potential to control the disease by lowering its incidence.

Objective: This review aims to evaluate the association between the implementation of hepatitis B vaccination programs and reduction in disease incidence by summarizing the findings of previously available evidence.

Methodology: A systematic review of the literature was conducted based on a comprehensive search strategy implemented across different electronic databases including the National Library of Medicine (PubMed, and PMC) and Science Direct. Studies published from 2015 till now were included with a preference for cohorts, cross-sectional, comparative, and epidemiological studies. Studies with irrelevant outcomes and those published before 2015 were excluded. The relevant information was collected with the aid of a standardized data extraction form. The methodological quality and risk of bias were assessed through relevant techniques and the collected data was narratively synthesized followed by a systematic organization of findings.

Findings: The reviewed studies indicated that national hepatitis B vaccination programs implemented across various countries were associated with a significant reduction in the occurrence of the disease. Coverage of all three doses particularly among infants and younger children resulted in a noteworthy reduction in the rates of HBsAgas well as Anti-HBc both of which are the markers for HB infection. These findings can be used as a model to eliminate hepatitis B by lowering the burden of chronic and new infections.

Conclusion: The study concluded that the complete coverage of the hepatitis B vaccination program, particularly among infants and young children, is highly effective against the reduction of the disease incidence. Ongoing research strives to enhance the efficiency of hepatitis B vaccination programs to eliminate the disease by examining a variety of factors associated with HBV.

Introduction

Hepatitis B (HB) is a serious and life-threatening viral disease of the liver which is caused by the hepatitis B virus (HBV). It can be both acute (severe and short-term) and chronic (long-term) [1]. There are two main modes of transmission of HBV including horizontal transmission that occurs through contact with body fluids (such as saliva, blood, semen, and vaginal fluids) of an infected person, and perinatal transmission during infancy from the infectious mother to the baby or early childhood period when the immune system is not matured. Most chronic HBV infections globally occur through this mode [2,3]. Most individuals with acute hepatitis B remain asymptomatic and stay unaware of their disease status for years. Only a small proportion of people with acute hepatitis have symptoms. The most common symptoms can include abdominal pain, jaundice, nausea, and extreme fatigue [4]. Chronic infections caused by hepatitis B virus can place

individuals at a high risk of death from liver cancer (hepatocellular carcinoma) and cirrhosis. Therefore, it is a critical health problem globally. According to estimates, 296 million individuals in 2019 were living with chronic HB, with 1.5 million newly acquired, acute infections each year [1]. It is a main cause of mortality and morbidity particularly in Africa and Asia with nearly three-quarters of the global chronic HBV cases found in these regions. Hepatocellular carcinoma due to chronic HBV remains a major issue with incidence rates of 11.4 to 17.2 per 100,000 persons for women, and 37.9 to 47.1 per 100,000 persons for men [5].

In the clinical expression, the primary determining factor of acute HBV infection and the progression of chronic disease is the age of acquiring the infection. Less than 10% of children under 5 years with acute infection have initial signs of disease in comparison to 30% of infections in adults. While the risk of chronic disease has an inverse relation with age. Chronic infections occur in eighty to ninety percent of infants who get infected in the first year. Contrarily, 30-50% of children who acquire infection before 6 years, and nearly 1-5% of adults develop chronic HB infection [6,4]. The main risk factors or behaviors for symptomatic, acute HBV infection are injection-drug use and sex with multiple partners [7]. Other risk groups may include hemodialysis patients, household members of an infected individual, developmentally disabled individuals in long-term care settings, incarcerated individuals, travelers to regions with HBV endemicity, and individuals at risk of occupational exposure [4]. Strategies to prevent HBV infections include medical treatment of patients with chronic infections, interruption of the route of transmission, and vaccination of susceptible persons [8]. Among these, vaccination or immunization is the most effective strategy that prevents people from contracting hepatitis B infection. Vaccination has been proven the most effective control strategy for HB globally since the initial period. The earliest plasma-derived vaccines were used for more than 30 years. Later on, the vaccine component which is the sub-viral particle expressing the HBV surface antigen (HBsAg) was substituted by antigen developed in yeast. However, both types of vaccines are highly safe and effective [9,10]. The recommended dose of vaccination by the World Health Organization (WHO) to develop complete immunity is three doses. WHO pursues its goal to eliminate the hepatitis B virus infection by the year 2030, to decrease the likelihood of new, chronic HB by 90%, and to reduce the mortality of this disease by 60%. Hepatitis B vaccination has a vital role in the achievement of this vision as the successful implementation of the HBV vaccination program has a high potential to eliminate the disease as a serious public health concern [11].

Vaccination for hepatitis B is available for all age groups. It is recommended for every individual including infants, adolescents, or children under the age of 19 years who have not been vaccinated in infancy, adults between the ages of 19 and 59 years, and older adults of age 60 years and above who have risk factors for acquiring HBinfection [12]. Universal vaccination programs have shown a noteworthy decline in HBsAg prevalence, diseases caused by acute and chronic HBV infections [13,14], and hepatocellular carcinoma incidence [15-17]. Subsequently, hepatitis B vaccination is a highly effective measure for the primary prevention and control or management of HBV infection. More than 179 countries have adopted HBV immunization in their routine vaccination programs with remarkable outcomes [18]. In summary, hepatitis B vaccination is potentially effective in the fight against HBV infections. It helps in the prevention of contracting the infection, and thus, plays a vital role in lowering the overall disease burden. Considering this, this systematic review study is aimed at investigating the link between the implementation of HB vaccination programs and a decrease in disease incidence.

Methodology

Research Question

The generated research question is "What is the association of hepatitis B vaccination programs with the reduction of the disease incidence?"

Development of Search Strategy

A comprehensive research strategy was developed using appropriate keywords along with database-specific indexing terms related to "hepatitis B", "vaccination programs", "disease incidence reduction" and "effectiveness". Boolean operators "AND" and "OR" were used to generate a variety of combinations of the above-mentioned keywords.

Inclusion and Exclusion Criteria

Inclusion Criteria: Studies assessing and reporting the effectiveness of hepatitis B vaccination programs against disease incidence reduction. Cohort studies, cross-sectional studies, comparative studies, epidemiological studies. Studies published in the English language, between 2015 and 2023.

Exclusion Criteria: Review studies, editorials, case reports, letters, and studies reporting irrelevant outcomes (i.e. decrease in disease incidence). Studies published in other languages than English and before 2015.

Database Selection and Search

The search was executed across electronic databases including the National Library of Medicine (PubMed, and PMC) and ScienceDirect databases. Screened titles and abstracts for relevance to the review question based on the inclusion and exclusion criteria. Full-text articles were retrieved for highly relevant studies by assessing their suitability for inclusion.

Data Extraction

The relevant information from the included studies was collected by developing a structured data extraction form. Extracted data based on the research characteristics (year, authors, study design), demographics of participants (particularly the age), hepatitis B vaccination program implementation period, and their effectiveness in terms of

decrease in the disease incidence.

Quality Assessment

Used appropriate tools for assessing the quality of included studies. Evaluated the risk of bias (ROB), potential sources of bias within each study, and their methodological quality.

Synthesis and Analysis of Data

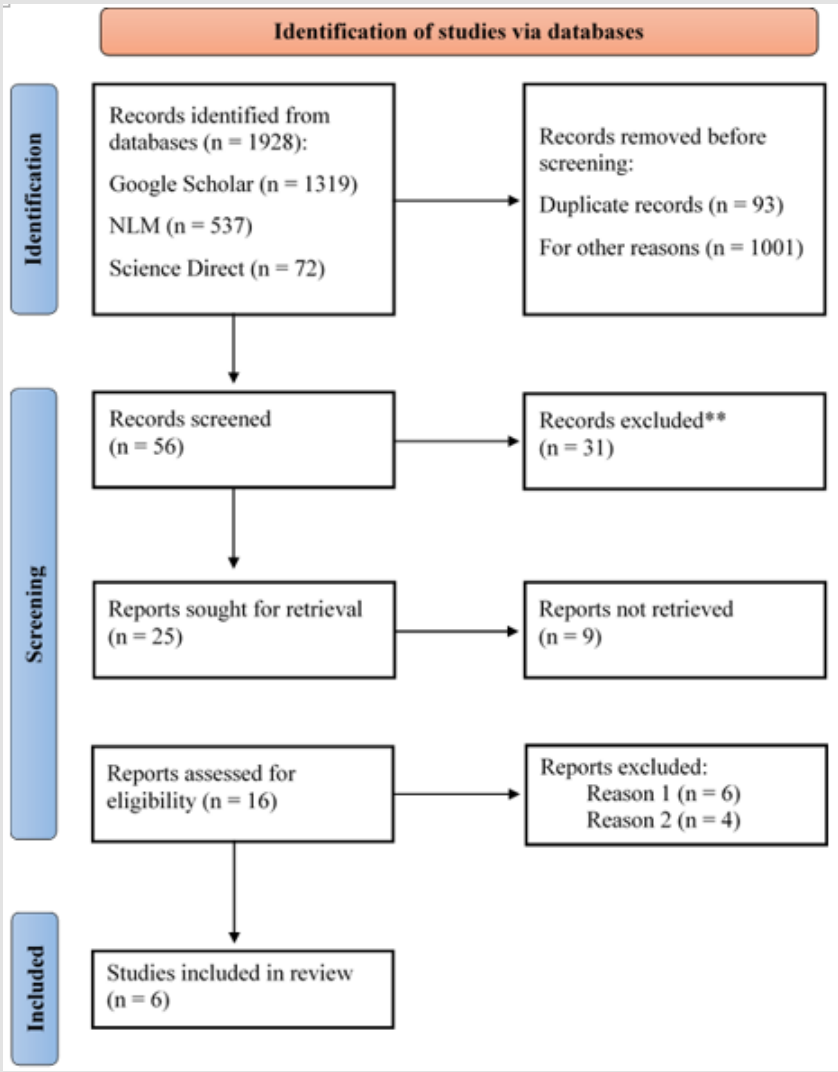
The extracted data was synthesized narratively, and findings related to the implementation of the HB vaccination program and effectiveness towards decrease in the disease incidence were organized systematically. Performed sensitivity analyses and subgroup analyses if applicable.

Interpretation of Findings

Interpreted results based on limitations and strengths of the included studies. Discussed practical implications, identified gaps in knowledge, and provided recommendations for future research.

Report Writing

Developed the systematic review manuscript based on PRISMA (Preferred Reported Items for Systematic Reviews and Meta-Analysis) guidelines. Organized the paper under clear sections including Introduction, Methodology, Results, Discussion, and Conclusion (Figure1).



Note: *Reason 1 = Irrelevant to the review question.
*Reason 2 = Low quality

Figure 1: PRISMA Chart.

Excluded Studies (Table 1) [19-28]

Table 1: Excluded studies with reasons.

Sr. No.	Author(s) Name and Year	Title	Reason to Exclude
1	Miao, et al. [19]	Enhanced sentinel surveillance for hepatitis B infection in 200 counties in China, 2013-2016	Irrelevant outcome focuses on the impact of enhanced surveillance of vaccination programs on disease incidence rather than the direct association between vaccination programs and the impact of disease incidence
2	Patrick, et al.m [20]	Elimination of acute hepatitis B among adolescents after one decade of an immunization program targeting Grade 6 students	Very old study
3	Ropero Álvarez, et al. [21]	Progress in vaccination toward hepatitis B control and elimination in the Region of the Americas	Focuses on vaccination program coverage, implementation, and progression, review-based reporting about the association of vaccination with disease prevalence reduction
4	Harpaz, et al. [22]	Elimination of new chronic hepatitis B virus infections: results of the Alaska immunization program	Very old study
5	Huang, et al. [23]	The impact of hepatitis B vaccination status on the risk of diabetes, implicating diabetes risk reduction by successful vaccination	Irrelevant outcome focuses on the link between HB vaccination and reduction of the risk of diabetes
6	Wu, et al.m [24]	Association between vaccine dose and risk of hepatitis B virus infection in Fujian Province, China	Irrelevant study measures assess the link between the dose of vaccine and the risk of HBV disease, not directly related to the question of this systematic review
7	Van Buren, et al. [25]	Hepatitis B virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Immunization Practice Advisory Committee (ACIP)	Very old study
8	Bhimma, et al. [26]	The impact of the hepatitis B virus vaccine on the incidence of hepatitis B virus-associated membranous nephropathy	A very old study, irrelevant outcome, focuses on the effect of the HB vaccination program on the decrease in the rate of membranous nephropathy
9	La Torre, et al. [27]	An assessment of the effect of hepatitis B vaccine in decreasing the amount of hepatitis B disease in Italy	Not a very recent study
10	Cui, et al. [28]	Factors associated with the effectiveness of the first dose of hepatitis B vaccine in China: 1992-2005	Irrelevant study measures focus on identifying the determinants of the effectiveness of HB vaccine dose not a direct association between vaccination and the impact of disease incidence

Results (Table 2) [29-34]

Table 2: Studies included for results.

Sr. No.	Author(s) Name and Year	Study Design	Location	Participants (age)	Findings
1	Chiang, et al. [29]	Cohort study	Taiwan	Children and adults, Age between 5 and 39 years	Significant reduction in the occurrence of chronic HB infections in individuals with hepatocellular carcinoma from 83.3% (birth cohorts from 1980-1984) to 55.6% (birth cohorts from 2000-2004)
2	Mokhtari, et al. [30]	Cross-sectional study	Shiraz (Iran)	Male and female adults (mean age ±26 years)	A significant association between the vaccination status of individuals and a decrease in the incidence of HBV infection with P value = 0.023
3	Moghadami, et al. [31]	Retrospective cohort study	Iran	Vaccinated Unvaccinated group = 26-50 years group = 17-24 years	Significant decrease in the HBV infection rate in the vaccinated group (5.9%) than the unvaccinated group (8.3%) with P value = 0.017

4	Sun, et al. [32]	Epidemiological survey	China	Full coverage = 0 to 15 years Partial coverage = 15 to 20 years No coverage = more than 20 years	HB prevalence in 2010 differed significantly among the three groups with P value less than 0.001.
					ṁ m m Incidence among full coverage group = 8.96/ 100,000
					ṁ m m Incidence among partial coverage group = 53.9/ 100,000
					ṁ m m Incidence among no coverage group = 110.3/ 100,000
5	Posuwan, et al. [33]	Serosurveys	Thailand	Between 6 months and 60 years	Significant reduction in the HBV infection incidence before and after the vaccination program (P value < 0.001)
					A significant difference between the rate of seropositivity for HBsAg in post-vaccination group (0.6%) and pre-vaccination group (4.5%)
6	Salama, et al. [34]	National community-based cross-sectional survey	Egypt	Fully vaccinated children aged between 9 months and 16 years	The occurrence of viral HB infection among younger children was significantly lowered than the older children (above or equal to 7 years) with P value < 0.001

It appears that the research carried out by Chiang et al. [29] examined the cohort association of the implementation of a national vaccination program against hepatitis B in 1984 and an anti-viral therapy program in 2004, and the occurrence of HB infections (ESLD – End-Stage Liver Disease) in Taiwan. Findings suggest that immunization programs significantly decreased the incidence of chronic HBV infections from nearly 83% for individuals with liver cancer born between 1980 and 1984 to about 55% for those patients born between 2000 and 2004. Additionally, this program also resulted in a sharp reduction in cohort association from the 1982-1986 birth cohorts to the 2007-2011 birth cohorts revealing decreases in incidences of chronic liver disease (CLD) mortality (by 82%), liver cancer mortality (by 63%), and liver cancer incidence (by 80%). These findings imply that a combination of an HB vaccination program and an anti-viral therapy program is substantially effective in decreasing the prevalence of chronic HB infections including liver cancer, ESLD, and related mortality. The study by Mokhtari et al. [30] identified the relationship between routine hepatitis B vaccination and viral HB infection in a city in Iran. They evaluated various factors including demographic variables, vaccination status, and potential risk for infection. The study outcomes suggest that family history is the main risk factor, while the vaccination status of individuals is the main protective factor against HBV infection. Participants who received complete doses (three) of the vaccination program had lowered the chance of developing hepatitis B by 43% (P =0.004). This implies that full coverage of the vaccination program is significantly associated with lowering the HBV disease incidence.

Moghadami et al. [31] reported the efficiency of a national infantile vaccination program for HB in Iran by highlighting the rate of HBsAg and Anti-HBc (antibody to hepatitis B core antigen) as the markers of the infection. Their findings show that the prevalence of HBsAg differs non-significantly among vaccinated and unvaccinated cohorts, however, rates of Anti-HBc lowered significantly among the vaccinated cohort than the unvaccinated. Considering these two markers of infections, the study reported a significant decline in the prevalence of HBV among the vaccinated cohort as compared to the unvaccinated. Moreover, HBsAg prevalence gradually reduced from 3.5% to 0.6% before and after implementing the vaccination program respectively. These results indicate that HB vaccination has a noteworthy impact on lowering the rates of HBsAg carrier among individuals thereby decreasing the overall incidence of chronic HBV infection.Another study by Sun and colleagues [32] evaluated the influence of infantile vaccination programs for HB by analyzing differences in the disease incidence according to the vaccination coverage in China. Based on vaccination coverage, participants were divided into three groups including complete coverage (0 to 15 years of age), partial (15 to 20 years), and no coverage at all (above 20 years of age). Results indicated that the rate of new HBV infection was considerably lowered among children (below 15 years) with full coverage in comparison to partial or no coverage groups. Furthermore, low coverage of vaccination programs is linked significantly with the greater incidence of new infections. In addition, the prevalence of HBV was 15.8/ 100,000 in covered children who were 0-9 years of age in 2004, which reduced to 6.36/ 100,000 in 2010 after the implementation of the program revealing a statistically significant difference with P value below 0.001. These results imply that complete coverage and promotion of the hepatitis B vaccination program is of high significance for a successful drop in the incidence of HB.

The seroprevalence surveys conducted by Posuwan, et al. [33] also revealed a statistically significant decrease in the prevalence of HB after the implementation of the hepatitis B vaccination program for neonates in Thailand. The carrier rate for HB virus among adolescents and children lowered significantly (from 5%-6% to less than 1%) after the implementation. HBV infection incidence in terms of detectable Anti-HBc also decreased remarkably post-implementation of the HB vaccination program. Salama, et al. [34] reported a significant

sero protection among children after implementing a compulsory HB vaccination program in Egypt. They showed that younger age (less than 5 years) acts as a significant factor for having seroprotective levels. Overall, the incidence of HBV infections lowered significantly with a P value less than 0.01 among younger children. This implies that the HBV vaccination program is highly effective in the declining incidence of hepatitis B as it provides adequate protection against the disease.

ROB of Included Studies

Fig presented above shows the ROB of studies included in this systematic review. Selection bias may arise in these studies for various reasons. Chiang et al.'s cohort study focused only on individuals aged between 5-39 years. Thus the research may not have been representative of the entire population of individuals with chronic HB. The cross-sectional study by Mokhtari et al. covered participants from Shiraz, Iran. Therefore, the study may not have been representative of the entire population of adults in Shiraz City Iran. Similarly, the findings of Moghadami et al.'s retrospective cohort study may not have been generalized to the entire population of people in Iran due to a limited sample size of 2256 participants. Studies by Sun et al. and Posuwan et al. may also not have been representative of the entire population in China and Thailand respectively. The study by Salama et al. covered vaccinated children from only six governorates in Egypt, and thus, may not have been a representative of the entire population of children in Egypt. Furthermore, it is important to note that these are some of the potential biases that might affect the outcomes of these selected studies. The specific risk of bias for individual studies may vary based on the study population, design, and methodology.

Discussion

The objective of full-text screening of the selected studies was to evaluate the association between the implementation of vaccination programs for hepatitis B and a reduction in the incidence of disease. Considering this, the study collected and summarized evidence from the existing literature supporting the effectiveness of HB vaccination programs in lowering the disease burden. In the reviewed studies, researchers sought to provide valuable insights into the link between HB vaccination programs with a decrease in the rate of disease occurrence by conducting cohort studies and cross-sectional, and seroprevalence surveys in various countries. The effectiveness of vaccination programs against the incidence of hepatitis B is demonstrated by their significant impact on the rates of HBsAg and anti-HBc markers among the studied populations. The main findings suggested that the implementation of national vaccination programs against hepatitis B is an effective strategy to lower the incidence of HBV infections including the rate of chronic infections as well as the new cases. These programs are equally effective in lowering the incidence of CLD and liver cancer resulting from chronic HB infections, and the related mortality rates. Moreover, it is found that the complete coverage of vaccination (three doses), especially during infancy and childhood is more effective in controlling the disease incidence. Subsequently, this systematic review concluded that a drop in the incidence of hepatitis B is significantly associated with the effective implementation of HB vaccination programs with complete coverage particularly among infants and younger children, indicating the potential of hepatitis B vaccination programs for long-term results in terms of the eradication of the disease.

Similar findings have been reported by several previous studies. Lin and Wong [35] demonstrated that the HB vaccination program implemented in 1988 in Hong Kong resulted in the reduction of the reported cases of acute HB infection from 250 to 41, from 1988 to 2014 respectively. Another research by Cui, et al. [28] showed a substantial decrease in the incidence of anti-HBc from 31.5%-41.9% to 2%-3% pre-and post-implementation of a national HB vaccination program with full coverage in China. Miao, et al. [19] stated that the enhanced surveillance of the national vaccination programs against hepatitis B in 200 countries resulted in a remarkable decline in the proportion of hepatitis B from 6.7/ 100,000 between 2009 and 2012 to 3.1/ 100, 000 between 2013 and 2016. Overall, the reviewed studies emphasize the usefulness of HB vaccination programs in reducing the incidence of HBV infections. The evidence collected from these studies is important for informing healthcare professionals, clinical practitioners, healthcare policymakers, and global public health organizations about the timely implementation of hepatitis B vaccination programs while properly screening the susceptible groups to successfully control the disease burden. This evidence can assist in the upgradation and improvement of vaccination strategies in healthcare settings to enhance protection against hepatitis B and improve the health status of patients with acute or chronic HB infection as well as the prevention of new infections.

While the studies provided invaluable insights into the effectiveness of hepatitis B vaccination programs in lowering the disease prevalence, there are certain limitations to consider: The majority of studies focused on hepatitis B vaccination programs for neonates or infants which may limit the generalizability of results to adults or other at-risk populations such as pregnant women and individuals with risk of developing HBV infection. Moreover, studies by Chiang, et al. [29] and Mokhtari, et al. [30] evaluated only several factors (age, vaccination status) linked with HBV disease. Therefore, these studies do not provide evidence related to various factors that may impact the effectiveness of HB vaccination programs in lowering disease incidence. Another limitation is related to the follow-up period. Some studies had a short follow-up duration; however, others did not include any follow-up period. A longer follow-up period is essential to properly assess the association between the implementation of an HB vaccination program on the long-term reduction of the incidence of the disease. These limitations must be considered in future research to provide more comprehensive and insightful results on the effectiveness of vaccination programs against the successful control of hepatitis B.

Interpretation of Main Outcomes as Physiological Plausibility

The main outcomes of the study support the physiological plausibility of the effective relationship between HB vaccination and the reduction in disease incidence. Findings from studies by Moghadami, et al. [31], Posuwan, et al. [33] and Salama, et al. [34] highlighted a considerable reduction in the proportions of HBsAg and anti-HBc both of which are recognized among the crucial markers for the infection. HBsAg is the primary marker of the infection linked with high HB viral load, whereas anti-HBc is a marker of acute infection caused by HBV when HBsAg is absent [37]. Reduction in both of these markers is associated with lower rates of HBV carriers and thus, a decrease in the incidence of chronic and acute HB. Similar impacts of hepatitis B vaccination programs are reported in the studies by Cui, et al. [28], Zhao, et al. [34], and Weisen, et al. [37].

Clinical Plausibility of Results

The review outcomes support the clinical plausibility of the effectiveness of HB vaccination programs in the prevention of viral hepatitis B. Timely implementation of HBV vaccination during infancy and childhood period, and among the high-risk groups including individuals at risk for developing the infection can help in the reduction of the new cases of infections nearly to zero which can eventually result in the complete eradication of HB disease in the future [14]. Clinical practitioners and healthcare workers can play a vital role in this regard by screening the susceptible individuals and identifying those at-risk thereby providing them with appropriate counselling and guidance for vaccination.

Implications of Main Results

The implications of the main outcomes of the current study indicate that the existing universal HB vaccination programs are protective and highly effective in controlling the occurrence of HBV infections. In particular, ensuring the complete coverage of vaccination and timely dose during infancy is significantly associated with controlling disease incidence and lowering the rate of new infections. Proper implementation of the HB vaccination program has a substantially high potential to increase the sero protection against HBV thereby decreasing the incidence of chronic infections caused by HBV [19, 28], ESLD, and liver cancer as well as the rate of mortality linked with these diseases [29-34]. Given this, effective implementation of HBV vaccination programs not only reduces the burden of the disease and chronicity rates but also controls the related complications [18].

Future Perspectives

Moving forward, future studies should focus on all age groups including middle to older age adults with long-term follow-up periods to validate the outcomes and establish the long-lasting efficacy of hepatitis B vaccination programs for the successful reduction of the disease incidence globally. In addition, evaluating possible factors linked with hepatitis B infection among different risk groups can provide further insights regarding the optimization of the immunization approach for preventing new infections. Moreover, exploring the cost-effectiveness and accessibility of HB vaccination and clinical care in various healthcare settings can help in large-scale coverage and implementation of these vaccination programs.

Conclusion

To conclude, studies included in the systematic review provide sufficient evidence regarding the success of the implementation of a vaccination program against hepatitis B and a decrease in the prevalence of the disease. The main outcomes suggest that complete coverage (three doses) of HB vaccination is substantially linked with the reduction in the occurrence of HB burden as well as the associated complications such as the occurrence of mortality caused by chronic disease and liver cancer. In addition, immunization during infancy, and childhood or adolescence period (among younger children) is more effective in controlling the incidence of hepatitis B as compared to the at-risk adult population. Ongoing research strives to enhance the efficacy of HB vaccination programs to eliminate the disease by examining the variety of factors associated with HBV.

Limitations

1. Focus only on vaccination programs for neonates and infants.
2. Unavailability of data on the evaluation of a variety of risk factors linked with HBV infection.
3. Lack of long-term follow-up time in cohorts

Recommendations

1. Conduct large-scale age cohorts of individuals with prolonged hepatitis B infection.
2. Evaluate the effectiveness of hepatitis B vaccination programs for older adults and other high-risk groups.
3. Explore a large number of potential risk factors for hepatitis B that may influence the success of a relevant vaccination program.
4. Include long-term follow-up time.
5. Assess the cost-effectiveness.

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