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Review

Seroprotection after recombinant hepatitis B vaccination among newborn infants: A review☆

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ABSTRACT

Introduction: Hepatitis B vaccination starting at birth provides a safety net for infants exposed to hepatitis B virus (HBV) during delivery or in early life. Hepatitis B vaccine is recommended in the United States for infants prior to birthing facility discharge, and within the first 12 h of life for infants born to hepatitis B surface antigen (HBsAg)-positive mothers. We performed a literature review and summarized the response to recombinant hepatitis B vaccine among infants.

Methods: Studies published between 1987 and 2011 assessing seroprotection from recombinant hepatitis B vaccine starting within the first 30 days of life were eligible. Seroprotection was defined using an antibody to hepatitis B surface antigen (anti-HBs) threshold of 10 mIU/mL at series completion. Infant seroprotection was compared in trial arms varying by maternal hepatitis B antigen status (e antigen [HBeAg], HBsAg), hepatitis B immune globulin (HBIG) administration, birth weight, vaccine dosage, schedule, and age at first dose.

Results: Forty-three studies were included. The median seroprotection proportion overall was 98% (range 52%, 100%). The final median seroprotection proportions did not vary appreciably by maternal HBsAg status, HBIG administration, or schedule. Higher compared to lower dosage resulted in earlier increases in anti-HBs but not in final seroprotection proportions. Infants with birth weights <2000 g compared to ≥2000 g had lower median seroprotection proportions (93% and 98%, respectively). Median seroprotection proportions were also lower when infants with birth weights <2000 g were vaccinated at 0–3 days of age compared to 1 month of age or older (68% versus 95%, respectively).

Conclusion: High levels of protection from recombinant hepatitis B vaccine are achieved in term infants vaccinated at birth, effectively preventing transmission of HBV and resultant morbidity and mortality. Implications, if any, for long-term protection are unknown for differences in responses among infants vaccinated at birth compared to ages older than 1 month.

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Contents

1. Introduction

Chronic hepatitis B virus (HBV) infection is one of the leading causes of liver failure and cancer worldwide [1]. Chronic HBV infection occurs in approximately 90% of infected infants, in contrast to fewer than 5% of persons infected at 5 years of life or older [2]. Historically, perinatal or childhood transmission accounted for 30–40% of chronic HBV infections in the United States [2]. Pregnant women with acute or chronic HBV infection are an important source of hepatitis B for their infants. Although a small proportion of infants are infected in utero, exposure to

Abbreviations: ACIP, Advisory Committee on Immunization Practices; AGA, appropriate for gestational age; anti-HBs, antibody to HBsAg; BW, birth weight; CDC, Centers for Disease Control and Prevention; EIA, enzyme immunoassay; GMT, geometric mean titer; HBeAg, hepatitis B e antigen; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; mIU/mL, milli-international units per milliliter; RIA, radioimmunoassay; SRU, sample ratio units; WHO, World Health Organization.

☆ The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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blood or body fluids during birth is a major route of transmission for HBV infection among infants [3]. Early life transmission also occurs through contact with infected siblings or care providers who may be unaware of their infection [4–8]. Although chronic HBV infections acquired in early life are largely asymptomatic, up to a quarter of these infections result in premature death from complications including cirrhosis, liver failure, or liver cancer [9]. Persons with chronic HBV infection are the main reservoir for transmission [2,10].

The first hepatitis B vaccine consisted of plasma-derived hepatitis B surface antigen (HBsAg). In 1982, the Advisory Committee on Immunization Practices (ACIP) recommended administration of hepatitis B immune globulin (HBIG) for infants born to HBsAg-positive mothers, followed by hepatitis B vaccination beginning at three months of age [11]. Clinical trials were structured so that infants received the initial dose of vaccine at birth, followed by completion of a 3 or 4 dose vaccine series [12–14]. Among high-risk infants, the efficacy of plasma-derived vaccine plus HBIG ranged from 66% to 100% [15].

Recombinant hepatitis B vaccines containing yeast-derived HBsAg replaced the plasma-derived vaccines in the United States by the late 1980s. Hepatitis B vaccination has been universally recommended for infants in the United States since 1991. The recommendation specified administration of the first dose by 2 months of age, with a preference for administration before birthing facility discharge [16]. In 2005, an update to the recommendation specified the first dose should be a "birth dose," i.e., administered to infants with birth weights ≥2000 g before birthing facility discharge as a safety net for early life prevention of HBV infection, or to all infants born to HBsAg-positive mothers within 12 h of birth [2]. As such, hepatitis B vaccination starting at birth is unique from other routine infant immunizations recommended in most countries that commence at 6 weeks to 2 months of life or later [17]. Prevention of perinatal or early life HBV infection underlies the recommendation for hepatitis B vaccination starting at birth.

Primary infant hepatitis B vaccination in the United States consists of three doses of 5 or 10 μg of monovalent recombinant vaccine administered intramuscularly on a 0, 1–2, and 6–18 months schedule. Other schedules are available in the United States (Table 1). Either of two monovalent vaccines (Recombivax HB® [Merck & Co, Inc., Whitehouse Station, NJ, US] and Engerix-B® [GlaxoSmithKline Biologicals, Rixensart, Belgium]) may be used. Combination vaccines may be used for doses administered at ages 6 weeks or older provided other indications are heeded [2].

In this review, we summarize the seroprotection proportions and immunogenicity of recombinant hepatitis B vaccine found in trials that administered recombinant hepatitis B vaccine starting within the first 30 days of life. We highlight some of the issues and gaps in knowledge related to the widespread use of hepatitis B vaccine for prevention of perinatal and early life acquisition of HBV infection.

2. Materials and methods

2.1. Search strategy

An electronic search of MEDLINE (via PubMed) and EMBASE (via Ovid) using combinations of search terms (hepatitis b vaccin*, hbv vaccin*, hepatitis b immuni*, hbv immuni*, immunogeni*, immune response, antibody, neona*, infan*, birth) was performed, including errata. Limits included publication date from January 1, 1987 (1988 for EMBASE) through December 16, 2011, English language, humans, and age birth through one month (through one year for EMBASE), without restriction for country where the trial was carried out. A manual review of personal files and reference lists from published studies was conducted concurrently.

2.2. Inclusion criteria

Published studies with a primary focus of reporting seroprotective (defined using an antibody to hepatitis B surface antigen [anti-HBs] threshold of 10 mIU/mL) response to monovalent recombinant hepatitis B vaccine administered to infants in the first 30 days of life were included.

2.3. Exclusion criteria

Studies were excluded when seroprotection was assessed in conjunction with administration of other vaccines, when a combination vaccine containing HBsAg was administered, or when vaccine was not administered intramuscularly. When two studies reported results for duplicate subjects, one study was excluded. Studies also were excluded when seroprotection was not reported within three months after the final dose in the series or when seroprotection using an anti-HBs threshold of 10 mIU/mL was not reported. Because of varying definitions, studies were excluded if antibody levels defining "seroconversion" or "seroprotection" were not reported. Studies were not excluded when a fraction of subjects meeting an exclusion criterion was deemed unlikely to affect the findings.

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