ORIGINAL ARTICLE
HEPATITIS B IMMUNIZATION IN THE MATERNITY WARD OF THE UNIVERSITY CLINIC FOR GYNECOLOGY AND OBSTETRICS IN R. N. MACEDONIA

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Abstract

Introduction: The beginning of the fight against infectious diseases is marked by receiving the first dose of Hepatitis B (HepB) vaccine in the maternity ward. It is a recombinant viral vaccine that stimulates active immunity. Unfortunately, on a global level, there is a decline in vaccination coverage of children for all vaccines. Our study aims to assess the coverage of the first dose of vaccine against the HepB among newborns in our hospital during 2023.

Material and Methods: This is a retrospective study and it included data for HepB vaccination from all newborns born at the University Clinic for Gynecology and Obstetrics from 01.01.2023 to 31.12.2023.

Results: There were 3,917 live births in total in our maternity hospital in the year 2023. 3,235 (82.6%) of the newborns were vaccinated against the HepB virus, while 682 (17.4%) of the newborns remained unvaccinated. In the first 24 hours after the birth and the first 7 days, 2,912 and 323 newborns were vaccinated respectively. Out of the 682 unvaccinated, 30 have been transferred to another health facility, 8 were unvaccinated due to the written consent from

the parents for postponing vaccination, and 644 newborns remained to be vaccinated in the vaccination dispensary, where individual calendars for immunization would be created.

Conclusion: In order not to lose the battle with infectious diseases at a time of intensive technical-technological development, it is necessary to be more active and to continuously participate in the process of immunization at all levels of the health care. Immunization of newborns with HepB vaccine is an effective measure to control HepB infection and prevent liver cirrhosis and hepatocellular carcinoma.

Key Words: *HepB infection, immunization, newborns, vaccine.*

Introduction

HepB virus is a DNA virus of the Hepadnaviridae family that causes infection of the liver. It is 50-100 times more infectious than Human immunodeficiency virus (HIV) and among the most resistant viruses in the external environment and disinfectants, with a very small infectious dose (0.00004ml), without a teratogenic effect.

Infection with the virus occurs by vertical transmission (from mother to newborn) and by horizontal transmission (by contact with blood and other body fluids) of an infected person. Whether the infection will be acute or chronic depends largely on the age at which it occurs. About 90% of infants, 20-50% of children aged 1-5 years and 5% of adult patients infected with the virus develop chronic infection. Around 25% of them will develop cirrhosis of the liver and 5% hepatocellular carcinoma (1,2). World Hepatitis Day is celebrated on July 28th, at which occasion the WHO published data about 1.1 million deaths as a result of HepB virus infection in 2023, 3 million newly infected each year, and over 300 million with chronic hepatitis infection B and C in the world (3). The most infected are in the African and the Western Pacific region, while in Europe, 14 million have chronic Hepatitis B infection or 1% of the population (Greece 3.4%, Romania 5.6%) (4). According to the data of the Institute for Public Health of the Republic of North Macedonia, the number of new infected cases, as well as cases with chronic HepB in our country is increasing (Table 1).

Table 1. Data from the Institute for Public Health of the Republic of North Macedonia.

	2020	2021	2022	2023
Infected with HepB	37	29	43	56
HBsAg+	18	12	11	17
Infected with chronic HepB	5	5	17	26
Deceased as a result of infection with HepB	0	1	5	2

The virus causes a silent epidemic, as 90% of infected people living with HepB are unaware that they have it. Timely information, prevention and treatment of the disease can reduce mortality from HepB infection.

Vaccination against the HepB virus in Macedonia began in October 2004, and soon reached the optimal level of 95% coverage of the population. According to the official data by the Ministry of Health of the Republic of North Macedonia (5) – HepB vaccine coverage with all three doses is given in Table 2.

Table 2. HepB vaccine coverage, data by Ministry of Health of the Republic of North Macedonia.

	2020	2021	2022	2023
Fully vaccinated with HepB vaccine	83,6%	78,7%	84,1%	No data

Our study presents the data for receiving the first dose of vaccine against the HepB among newborns in the University Clinic for Gynecology and Obstetrics during 2023.

Material and Methods

This is a retrospective study performed at the University Clinic of Gynecology and Obstetrics that included newborns in a period from 01.01.2023 to 31.12.2023.

The study included newborns in term ($37^{0/7}$ – $41^{6/7}$), late premature ($34^{0/7}$ – $36^{6/7}$) and premature newborns smaller than $34^{0/7}$ week of gestation.

All newborns with transfer to another health facility – hemodynamically unstable with complex congenital heart anomalies or respiratory unstable with the need for long-term mechanical ventilation – were excluded from the analysis.

Immunization with the first dose of the vaccine was carried out in the first 24 hours after birth, while for newborns with a birth weight below 2,000g, or smaller than the 34th week of gestation or with unstable vital parameters, the vaccine was given in the first 7 days at the latest. Immunization was carried out by intramuscular application of the Engerix vaccine, in a dose of 0.5ml, with a sterile needle 25G (length 16mm), in the area of the left m. vastus lateralis. The newborns were monitored for adverse effects of the vaccine during their stay in the Department of Basic Care. Newborns from HBsAg positive mothers received specific immunoglobulins 125 IU, in the first 12 hours after birth, on the contralateral side of the vaccine application, in the area of the right m. vastus lateralis. The same is recorded in the history of the newborn and in the birth certificate, as a document. For newborns whose mothers refuse immunization in the maternity ward, the parents were counseled and gave written consent for their decision.

Results

In the period from 01.01 to 31.12.2023 there were 3,917 live births in total at our maternity hospital. 3,235 (82.6%) of the newborns were vaccinated against the HepB virus, while 682 (17.4%) of the newborns were unvaccinated.

In the first 24 hours after birth, 2,912 newborns were vaccinated, including 6 from HBsAg+ mothers who received specific immunoglobulin in addition to the vaccine and 3 newborns from HIV positive mothers.

In the first 7 days of birth, 323 newborns were vaccinated, out of which 285 with asphyxia and/ or infection and/ or respiratory distress, and 38 newborns in the 34th week of gestation and/ or with a birth weight of less than 2,000 grams and are staying in the Department for basic newborn care.

There were 682 unvaccinated newborns in our maternity hospital, 30 of them have been transferred to another health facility (Children's Surgery, Cardio Surgery, Clinic for Children's Diseases), 8 were with written consent from the parents to postpone vaccination, and the rest 644 were discharged from the Intensive Care Unit (ICU). The parents of discharged newborns from the ICU, were advised to go to vaccination dispensary, where individual calendar for immunization would be created.

Discussion

Our study presents the actual situation with HepB vaccination in the 2023 year, and it is similar to the coverage described from several surrounding countries such as Albania and Bulgaria. All countries are committed to achieving the WHO strategic goal of the elimination of the vaccine-preventable disease.

The importance of the introduction of the HepB vaccination can be seen from the results and analysis of several studies. For example, a study by Petro et al. from 2014 (6), which included 2,670 newborns born in 1986, before the introduction of the HepB vaccine in maternity hospitals in Gambia, and 4,613 newborns born in 1990, after the introduction of the vaccine, showed massive reduction in the prevalence of chronic HepB infection as a result of the introduction of regular immunization with HepB vaccine. The effectiveness of vaccine is described to be 94% successful.

Additionally, the importance of the vaccination could be seen from other studies, such as the study by Shefa Al-Amleh (7) that determined the prevalence of HepB in children born from HbsAg positive mothers. The study included 125 HBsAg positive mothers of different ages who gave birth of in a total of 386 children. They found 42 (10.9%) HBsAg-positive children. Transmission was described to be higher among the lower socioeconomic class in rural areas of Palestine.

Although there was a global decline in the overall vaccination and the COVID-19 pandemic additionally affected this process, Dugovich et al. (8) in an analysis of a total of 8,000 newborns, at Children's Hospital, Charleston, South Carolina, concluded that the COVID-19 pandemic had no significant impact on the administration of the first dose of the HepB vaccine. Before the pandemic, immunization was 92.3% of 3,583 included newborns versus 90.9% of 3,928 newborns, so, there was a drop of 1.4%. Factors such as white race, married mothers, and TT below 2000g, had a greater impact on receiving the first dose vaccine than the COVID-19 outbreak itself.

According to WHO data on immunization against HepB globally, from the 2022 year to June 2023 (updated every July), 45% of the newborns were vaccinated with the first dose of HepB vaccine (in the maternity ward) and 84% of children with all three doses (9).

According to UNICEF data (10), for the same period, 97% of newborns were covered by the first dose in all maternity hospitals in R. N. Macedonia, and 84% of children with three doses. Compared to countries from our region, for example Serbia, 99% of newborns received the first

dose of HepB vaccine and 92% of children received all three doses. In Albania 99% of the newborns and 97% of children are vaccinated, and in Bulgaria 97% of the newborns received the first dose and 91% of children have received 3 doses of HepB. There are no official data for Montenegro and Greece, but the available data indicate a lower percentage of immunization with the other two doses of vaccine, which is probably due to a lower response to the vaccine, in the conditions of the Covid-19 pandemic (March 2020-May 2023).

The obtained data indicate an increased percentage of those vaccinated with the first dose of vaccine compared to data from previous years. According to our records, the first dose of the vaccine against the HepB virus in year 2022, at our maternity ward was received by 75.5% (3,146 newborns from 4,169 live births), compared to our survey for 2023 when 82.6% of live births were immunized.

Considering that the most complicated pregnancies and deliveries of extremely premature newborns are completed at our facility, there are still a lot of newborns that cannot be vaccinated at our hospital. Their immunization is carried out according to an individually created calendar depending on the correct age, in vaccination dispensaries. So, for these newborns we do not have much opportunity to increase the percentage of vaccination with HepB vaccine.

Unfortunately, globally, there is a declination in vaccination coverage for all children, for all vaccines, including immunization with the HepB virus vaccine. Not a single case of adverse reactions was observed after vaccination. Of course, there is room for improving the screening of pregnant women, the registration of HBsAg+ pregnant women, of newborns who received specific immunoglobulins in addition to the vaccine. With that, we are actively participating in the realization of the goals of the WHO, adopted at the 75th World Assembly in 2022 (11). The goals are to reduce the number of newly infected people with HepB by 90%, reduce the mortality caused by infection with the HepB virus for 65%, achieve coverage of newborns with the vaccine by 90%, and increase of the first dose of vaccine by 90% by 2030.

Primary vaccination in the maternity hospital is one of the steps on the way to the set goals. For a complete picture of vaccination coverage with HepB vaccine, data from revaccinations after one and after 6 months of primary vaccine in outpatient clinics are taken into account (12).

Conclusion

Despite the turmoil on the vaccination and immunization scene, the HepB vaccine is a safe and proven weapon in the fight against hepatitis infection and its sequelae. The enhanced and

continuous engagement of all health institutions and individuals involved in the immunization process leads to the achievement of high collective immunity and good control, as well as elimination and eradication of this infectious disease.

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