Non-Randomized Clinical Trial to Interrupt Vertical Hepatitis B Viral Infection

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Introduction: Hepatitis is an inflammation of the liver, the condition can be selflimiting or can progress to fibrosis, cirrhosis or liver cancer. Hepatitis viruses are the most common cause of hepatitis in the world but other infections, toxic substances (eg. alcohol, certain drugs), and autoimmune diseases can also cause hepatitis [1]. There are 5 main hepatitis viruses, referred to as types A, B, C, D and E. Hepatitis B (HB) C and D usually occur as a result of parenteral contact with infected body fluids. Common modes of transmission for these viruses include receipt of contaminated blood or blood products, invasive medical procedures using contaminated equipment and for HB transmission from mother to baby at birth, from family member to child, and also by sexual contact

Aim of the study: To assess the effectiveness of HB vaccine alone versus HBIG combined with HB vaccine in the interruption of neonatal HB viral infection.

Methods: The study was conducted in two localities in Gaza Strip (GS), the first was the Epidemiology departments, part of the preventive medicine directorate in the Primary Health Care (PHC) directorate in the Palestinian Ministry of Health (PMOH). There are five departments in GS. The second setting was the delivery rooms in the governmental hospitals in GS. The hospitals included in the study were Al-Shifa hospital, The European Gaza hospital and Nasser hospitals.

Results: All the infants were tested for HBsAg after nine months of age and all of them were negative, indicating that all of them were free from HBV infection. The Anti-HBs titers were normally distributed among the infants with a range of (3-1000 IU/L), it was 402.11 IU/L among the infants were given HB vaccine combined with HBIG in the maternity departments, Geometric Mean Titration (GMT) was 180.87 IU/L which was less than the infants immunized in the epidemiology departments with HB vaccine alone 428.52 IU/L GMT was 207.64 IU/L. With respect to the time of starting the immunization regimen directly post-delivery it was clear that babies received the regimen between 2-24 hours have the highest level of GMT 211.58 IU/L, with very little difference between the other two groups who vaccinated between 1-2 hours or after 24 hours of life with 182.05 IU/L and 184.11 IU/L respectively.

Conclusion: The present study is considered a preliminary non-randomized clinical trial about the prevention of neonatal HBV infection in Palestine.The study was conducted upon 228 neonates born to inactive HBV infected mothers, 114 to each group, 114 neonates vaccinated with HB vaccine alone in the five epidemiology departments in Gaza governorates and HB vaccine combined with HBIG given to the other 144 neonates in the obstetric departments at Al-Shifa hospital, European Gaza hospital, and Nasser hospital, directly after delivery. Blood testing for HBsAg and Anti- HBs titer was done to all infants after nine months of age.

Keywords

Prevention; HBV infection; HBIG, HB vaccine; GMT