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Question: Should hepatitis B vaccine at birth be used for prevention of sequelae from hepatitis B virus infection?

Setting: General population (global)

Conclusion: The evidence by outcome is as follows. 1) Moderate quality evidence to support effectiveness of HepB given within 24 hours of birth to prevent hepatitis B infection. 2) Low quality evidence to support effectiveness of HepB given within 24 hours of birth to prevent incidence of hepatocellular carcinoma. 3) Low quality evidence to support effectiveness of HepB given within 24 hours of birth to prevent mortality from hepatocellular carcinoma.

| Quality assessment | | | | | | Summary of Findings | Importance |
|---|---------------------|------------------------|--------------------------|--------------------------------------|------------------------|-------------------------------|------------|
| No of studies | Design | Limitations | Inconsistency | Indirectness | Imprecision | Quality | |
| hepatitis B virus infection (follow-up mean 18 months; blood specimen positive for HBsAg, HBeAg, anti-HBe) | | | | | | | |
| 5 ¹ | randomized trials | Serious ² | no serious inconsistency | no serious indirectness ³ | no serious imprecision | ⊕⊕⊕O ⁴ MODERATE | IMPORTANT |
| hepatocellular carcinoma (follow-up mean 10 years; registered HCC cases) | | | | | | | |
| 1 | observational study | no serious limitations | no serious inconsistency | no serious indirectness | no serious imprecision | ⊕⊕OO LOW | CRITICAL |
| HCC mortality (follow-up mean 10 years; deaths registered from HCC) | | | | | | | |
| 1 | observational study | no serious limitations | no serious inconsistency | no serious indirectness | no serious imprecision | ⊕⊕OO LOW | CRITICAL |

¹ RCTs fully addressed the issue of efficacy of HepB with HBV infection as an outcome. Only one observational trial has addressed the issue of efficacy against hepatocellular carcinoma (HCC) incidence and mortality. Since mortality from HCC is almost 100%, the two outcomes are highly correlated. This study was conducted in Taiwan, an area of high endemicity and where registration of new HCC cases and deaths was very complete. Therefore, this study was able to detect a change very early by measuring a change in HCC in children. Additional long-term efficacy studies are being established in Qidong Province of China and The Gambia. These studies have not reported results due to the long duration between HBV infection and cirrhosis or HCC.

² Randomization generation unclear in all studies. Allocation concealment unclear in 3/5. Losses to follow-up not described in all trials.

³ Four trials used PDV which is no longer available, one used RV.

⁴ Number of patients vaccine versus control: 33/252 (13.1%) vs 77/151 (51%). Relative effect (95% CI): RR 0.28 (0.2 to 0.4).

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