EE512

Economic Evaluation of Intradermal Hepatitis B Vaccination plus Imiquimod Pretreatment for Dialysis Patients

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Background

- Hepatitis B virus (HBV) infection presents a substantial threat to global public health, with complications such as liver failure, cirrhosis, and hepatocellular carcinoma (HCC).
- Maintenance dialysis patients are particularly vulnerable to HBV due to frequent blood product exposure, transfusions, and a compromised immune system.
- HBV vaccine response and durability are notably lower in these patients compared to healthy adults.
- Sci-B-Vac, a third-generation recombinant HBV vaccine expressing pre-S1, pre-S2, and S antigens, was shown in a double-blind, randomized controlled trial to be more effective intradermally (ID) with TLR7 agonist imiquimod pretreatment than intramuscularly in dialysis patients.

Objective

- This study aimed to evaluate the potential cost-effectiveness of ID hepatitis B vaccination with imiquimod pretreatment for dialysis patients from the perspective of US healthcare providers.

Methods

- **Patient Population:** a hypothetical cohort of serologically negative dialysis patients (on maintenance dialysis for at least 3 months) at 60 years old
- **Model:** A 15-year (lifetime) Markov model with a yearly cycle (Fig 1)
- **Compared vaccination strategies:** (1) ID HBV Sci-B-Vac with pre-treatment imiquimod cream (IMQ+ID group) and (2) IM HBV Sci-B-Vac (IM group)
- **Primary model outcomes:** hepatitis B-related events, direct medical costs, quality-adjusted life-years (QALY), and incremental cost-effectiveness ratio (ICER)

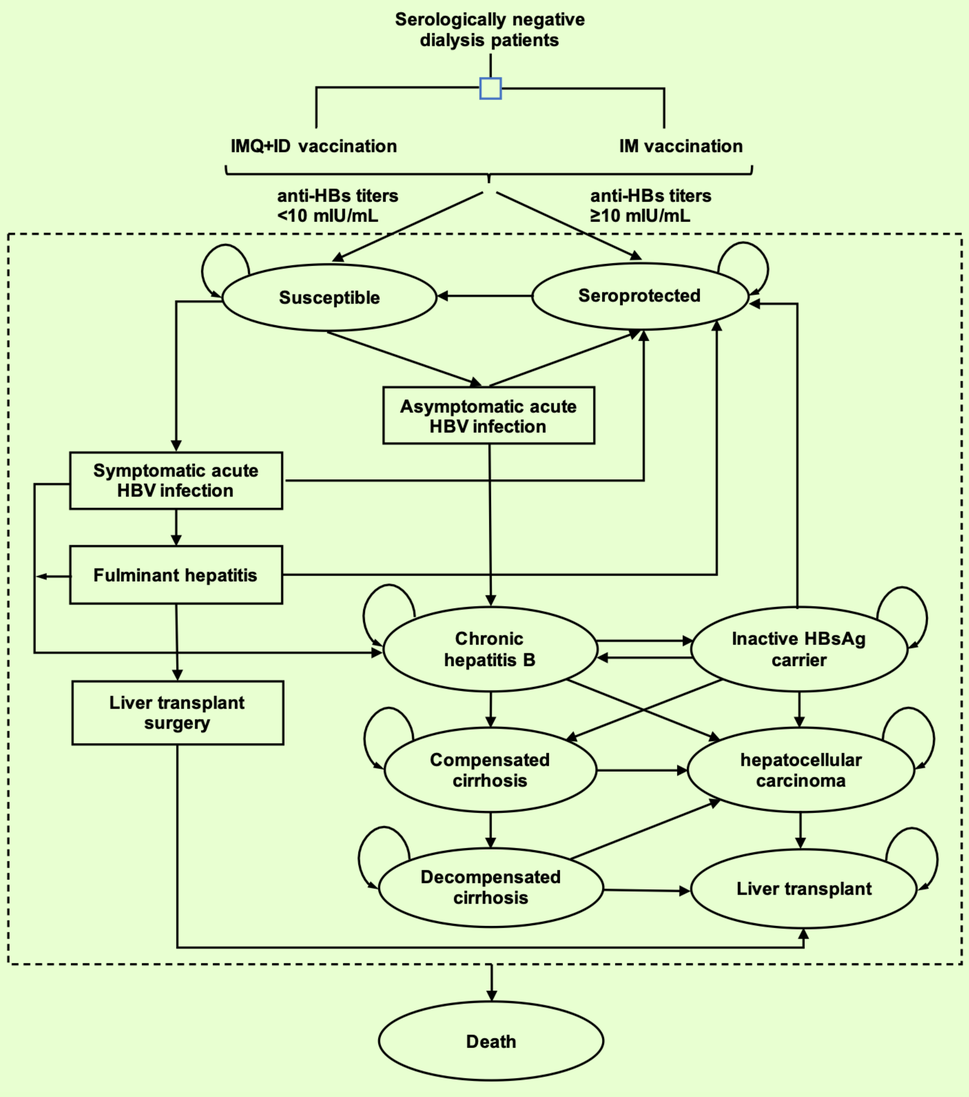

Fig 1 Simplified decision-analytical model structure

- **Model inputs:** derived from literature and public database
- **The IMQ+ID group was considered cost-effective if it resulted in:** (1) QALY gain and cost-saving, or (2) QALY gain at a higher cost and the ICER was lower than the willingness-to-pay (WTP) threshold
- **WTP threshold:** 50,000 USD/QALY gained
- **Sensitivity analyses:** One-way sensitivity analysis and probabilistic sensitivity analysis were performed to explore the uncertainty in this model

Results

- **Base-case analysis**

- Compared to the IM group, the IMQ+ID group reduced all hepatitis B-related event rates. The IMQ+ID group showed an incremental cost of USD 38.94 with 0.0023 QALYs gained. The ICER of the IMQ+ID group was (17,032 USD/QALY) lower than the WTP threshold (Table 1).

Table 1 Base-case results

Outcome	IM	IMQ+ID	Incremental
Hepatitis B-related events (per 100,000 vaccinated dialysis patients)			
Acute infection	802	204	-598
Fulminant hepatitis	20.0	5.1	-14.9
Chronic hepatitis B	214.5	54.5	-160
HCC	71.6	17.2	-54.4
Liver transplant	0.020	0.005	-0.015
death	129.7	29.7	-100
Cost per individual (USD)	287	326	39
QALYs per individual	2.9740	2.9763	0.0023
ICER, USD/QALY	/	/	17,032

- **One-way sensitivity analysis**

- The ICER of IMQ+ID remained to be less than the WTP threshold throughout the variation of all model inputs in the one-way sensitivity analysis.

- **Probability sensitivity analysis:**

- The mean QALYs gained by IMQ+ID group was 0.0022 QALYs (95% CI 0.002207-0.002237; p<0.01) with a mean incremental cost of USD41.64 (95% CI 41.27-42.01; p<0.01).
- The ICERs of IMQ+ID versus IM were lower than the WTP threshold in 90.51% of simulations (Fig 2). At the WTP threshold of 50,000 USD/QALY, the probabilities of the IMQ+ID and IM group being cost-effective were 90.34% and 9.66%,respectively (Fig 3).

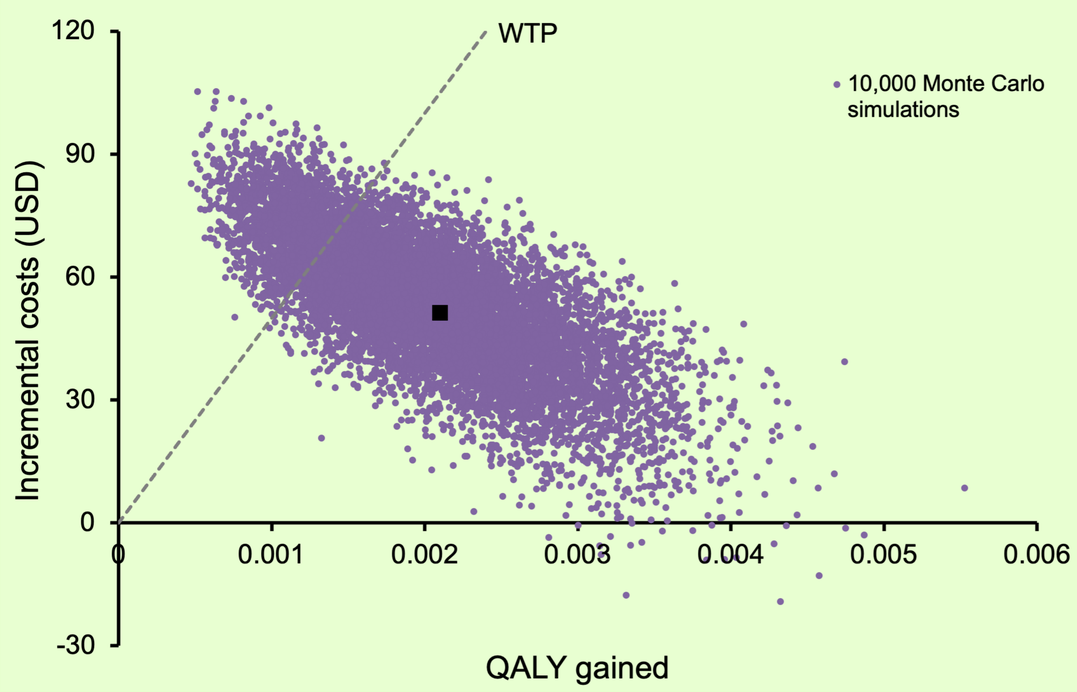

Fig 2. Scatter plot of incremental cost and QALYs

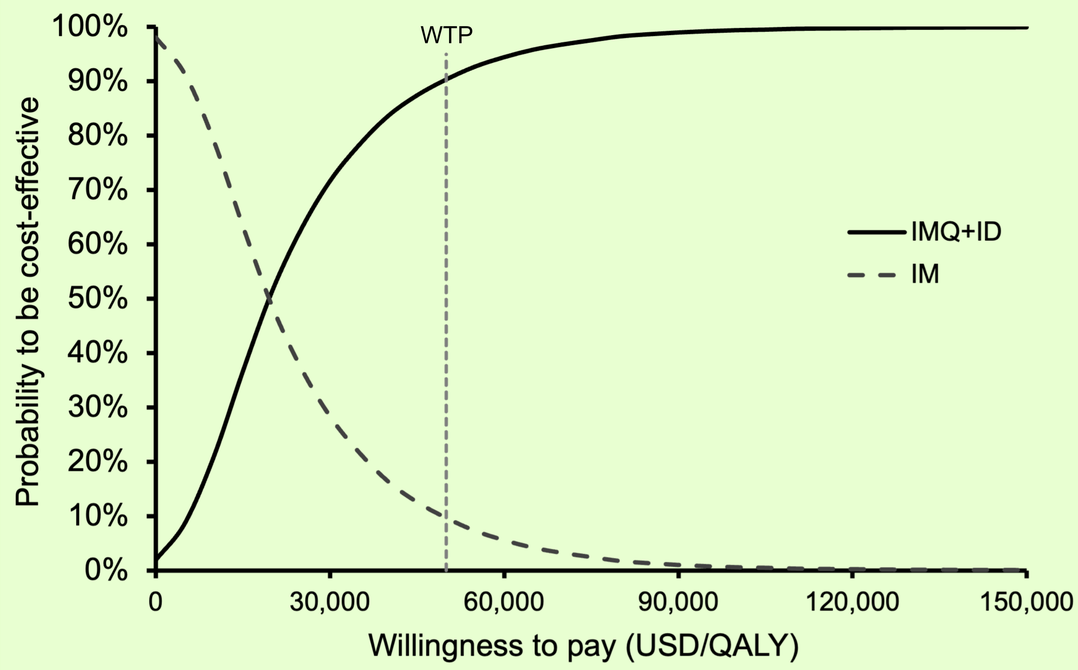

Fig 3. Variation in the probability of each vaccination strategy to be cost-effective

Conclusion

ID administration of HBV Sci-B-Vac with pre-treatment imiquimod cream in serologically negative dialysis patients appears to reduce hepatitis B-related events and was cost-effective from the perspective of US healthcare providers.

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