

STANDARD VERSUS DOUBLE DOSE OF HEPATITIS B VACCINE IN INFLAMMATORY BOWEL DISEASE: A RANDOMIZED TRIAL

Usha Dutta

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Double dose (40 µg) hepatitis B vaccination achieved significantly higher seroconversion rates than standard dose (20 µg) in IBD patients, with adequate immune response rates of 88.4% versus 55.6% (p=0.001).

KEY POINTS

- In this phase 3 RCT of 88 IBD patients randomized to standard (20 µg) or double (40 µg) dose HBV vaccination at 0, 1, and 6 months, double dose achieved significantly higher adequate immune response rates (anti-HBs >10 mIU/mL) of 88.4% versus 55.6% (p=0.001) and effective immune response rates (anti-HBs >100 mIU/mL) of 69.8% versus 46.7% (p=0.028).
- Among patients with active IBD, double dose produced markedly higher adequate immune response (87.5% vs 44%, p=0.001) and effective immune response (70.8% vs 32%, p=0.007) compared to standard dose.
- Multivariable analysis identified double dose as a positive predictor for both adequate immune response (OR 10.865, 95% CI 2.418-48.817) and effective immune response (OR 3.0, 95% CI 1.087-8.280), while biologic use was a negative predictor for both outcomes.
- No major adverse events occurred; 5 minor events (3 local injection site reactions, 2 systemic reactions with fever and myalgia) were reported across both groups.
- The study included 79 ulcerative colitis and 9 Crohn's disease patients; limitations include small sample size, limited representation of Crohn's disease and advanced therapies beyond anti-TNF biologics, and no assessment of immunity durability.

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