

## **Breaking the Barrier: Challenges in Hepatitis B Seroprotection Among Dialysis Patients**

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### **Background:**

The high prevalence of hepatitis B and C in the dialysis population is a significant concern in resource-limited settings. While advances in Hepatitis C treatment have mitigated its severity, Hepatitis B remains a critical challenge despite the availability of vaccination.

### **Methods:**

A retrospective review of hemodialysis data was conducted to assess seroconversion rates in patients vaccinated against Hepatitis B. All unvaccinated patients initiating hemodialysis were vaccinated using a modified-accelerated schedule of 40 µg inactivated HBsAg (Engerix B) on days 0, 7, 21, and 180 as per institutional policy. Anti-HBs levels >10 mIU/mL were considered indicative of seroprotection.

**Results:** Of the 39 patients with complete data (out of 86), 16 (41%) were negative for Anti-HBs. The mean Anti-HBs level in positive patients was 275 IU/L ( $\pm 353.98$ ), while it was 2.77 IU/L ( $\pm 2.71$ ) in negative patients.

**Conclusion:** Despite adherence to a super-accelerated vaccination protocol, a significant proportion of dialysis patients fail to achieve protective Anti-HBs levels, underscoring the need for tailored vaccination strategies and regular monitoring in this vulnerable population.

**Key Words:** Hemodialysis, cross infection, HBV, HCV, immunization, vaccination, seroconversion.

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### **Introduction:**

Regarding the seroconversion of dialysis population, the situation is worrisome in our population where cost constraints, lack of education of both patients and dialysis staff and frequent blood transfusions combine to provide a background where both hepatitis B and Hepatitis C may be transmitted and then spread through the dialysis rooms. The estimates of Hepatitis C seroconversion in local population is cited to be around 50%.<sup>1</sup>

Whereas recent advances in treatment of Hepatitis C mainly reduced its status to that of a common viral illness, Hepatitis B still remains a force to be dealt with<sup>2</sup>. However, the silver lining is the presence of vaccination against hepatitis B. The usual course (40 microgram at 0, 1, 6 months) is seen to give protective immunity in up to 93% of the vaccinees in general population, the effect of this vaccine in

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dialysis patients is not really up to the mark. For patients on dialysis, a generally accepted "protective" anti-HBs level is considered to be greater than 100 mIU/mL; however, due to their compromised immune system, some healthcare providers may aim for a higher level, and regular monitoring with booster doses may be necessary to maintain adequate protection against Hepatitis B infection<sup>3</sup>. However any patient with an Anti HBs level of less than 10 mIU/mL is considered to be non-immune and require a full course of re-vaccination.

The data for the prevalence of Anti HBs positivity in dialysis patients is lacking in our country. We aimed to analyze the data being collected as part of our hemodialysis database to answer this question.

### Methods

This was a retrospective review of data collected in our dialysis room. After approval of our local dialysis registry for reporting of data vide IRB certificate # FMH-25/03/2024-IRB-1377 we analyzed our data regarding hepatitis B virus vaccination.

As a protocol all of our patients initiating hemodialysis and not previously vaccinated against Hepatitis B are vaccinated as per institutional policy. We use a modified-accelerated vaccination schedule of 40 microgram inactivated HBsAg (Engerix B) on days 0, 7, 21 and a booster at 180 days instead of 365 days, for the last 10 years.<sup>4,5</sup> This is done in an effort to prevent incomplete schedules due to physician oversight or patient non-compliance. We described the patient to be Anti HBs positive if the Anti HBs level was more than 10 mIU/mL.

**Data analysis:** simple descriptive analysis was used to describe the data using SPSS 22, (IBM Corp., Armonk, NY). Data is presented as mean  $\pm$  standard deviation.

### Results:

A total of 39 patients had complete data out of 86 (45%) patients in our dialysis room. Of these 16 (41%) were found to be negative. The patients who were positive for Anti HBs had a mean of  $275 \pm 353.98$  IU/L and those who were negative had a Anti HBs level of  $2.77 \pm 2.71$  IU/L.

### Discussion:

The findings of this study highlight a critical gap in the seroprotection of the hemodialysis population against Hepatitis B in our setting. Despite institutional adherence to a super-accelerated vaccination schedule, 41% of the patients remained negative for Anti-HBs, which raises concerns about the efficacy of the vaccine in this vulnerable group. The significantly higher mean Anti-HBs levels in seropositive patients ( $275 \text{ IU/L} \pm 353.98$ ) compared to the negative group ( $2.77 \text{ IU/L} \pm 2.71$ ) underscores the variability in immune responses among dialysis patients.

This disparity in seroconversion may stem from the unique immunological challenges faced by individuals on hemodialysis. Chronic kidney disease (CKD), uremia, and the repetitive immune activation associated with dialysis are known to impair vaccine efficacy<sup>6</sup>. These factors, compounded by malnutrition and an overall state of chronic inflammation, diminish the body's ability to generate a

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robust immune response. Hence these patients may actually contract Hepatitis B during their day to day activities much more easily than the patients without CKD.

The results emphasize the importance of routine monitoring of Anti-HBs levels in dialysis patients, even among those who have completed the vaccination schedule. Patients with Anti-HBs levels below 10 mIU/mL are considered non-immune and require a full course of re-vaccination. However, for those with suboptimal levels (<10 mIU/mL), booster doses may be necessary to achieve and sustain adequate protection<sup>7</sup>. Additionally, implementing a protocol for regular serological testing and booster administration could help improve seroprotection rates in this population.

The prevalence of Hepatitis B and C in dialysis settings in our region remains alarmingly high, with Hepatitis C seroconversion rates cited at approximately 50%.<sup>1</sup> Factors such as cost constraints, lack of education, inadequate infection control practices, and the frequent use of blood transfusions contribute to this dire situation. Vaccination against Hepatitis B, though a critical preventive measure, cannot singularly counteract the risk posed by these systemic issues. Strengthening infection control protocols, minimizing blood transfusions, and educating patients and staff about transmission risks are pivotal steps to curb the spread of hepatitis in dialysis rooms.<sup>8</sup>

While advancements in the treatment of Hepatitis C have transformed it into a manageable condition, Hepatitis B continues to pose a formidable challenge.<sup>9</sup> The protective efficacy of Hepatitis B vaccination in the general population is well-established; however, the diminished response in dialysis patients underscores the need for tailored strategies. Modified-accelerated schedules with an early booster at 6 months rather 12 months in dialysis patients, as implemented in our study, may mitigate the risk of incomplete vaccination but must be paired with post-vaccination monitoring to ensure efficacy.<sup>5,10</sup>

This study is limited by its small sample size and the retrospective nature of the data, which may introduce selection bias. Additionally, the absence of long-term follow-up data precludes an assessment of sustained seroprotection over time. Expanding the sample size and incorporating longitudinal monitoring of Anti-HBs levels could provide more robust insights. The initiation of the current study where highlights that only 45.3% patients had complete data, also supports our resolve to cover this critical shortcoming.

Future studies should aim to identify predictors of poor seroconversion, such as age, nutritional status, and duration of dialysis, to develop targeted interventions. Investigating alternative vaccination strategies, such as double-dose schedules or the use of adjuvant vaccines, may also improve outcomes in this population.<sup>10</sup> Moreover, implementing a multicenter approach could provide a broader understanding of seroconversion rates and inform national vaccination policies for dialysis patients.

## Conclusion

The study highlights a concerning gap in Hepatitis B seroprotection among dialysis patients, despite adherence to a super-accelerated vaccination schedule. This underscores the need for routine Anti-HBs

monitoring, individualized vaccination strategies, and robust infection control practices to protect this vulnerable population from Hepatitis B infection.

**Conflict of Interest:** None Declared

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