

# Comparison of Hepatitis B Seroconversion Rates with Engerix-B and Recombivax-HB in Patients on Hemodialysis



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## Introduction

- Engerix-B<sup>®</sup> (GlaxoSmithKline, Atlanta, GA, USA) and Recombivax-HB<sup>®</sup> (Merck, Whitehouse Station, NJ, USA) are the two hepatitis B vaccinations approved by the FDA and currently used in end-stage renal disease patients in the United States.
- Previous studies indicated that seroconversion rates are significantly higher in people vaccinated with Engerix-B (ENG) versus Recombivax-HB (REC). The same has been reported in small studies in patients undergoing chronic hemodialysis.<sup>1-3</sup>
- The aim of this study was to further validate the potential different efficacy of the two vaccines in a large nationally representative population of hemodialysis patients from the USA.

## Methods

- All patients treated in Fresenius Kidney Care (FKC) clinics from January 2010 to December 2015 were included if they were negative for both hepatitis B virus surface antigen (HBsAg) and anti-HBsAg antibodies.
- After a complete vaccination course (4 doses of 40 µg for ENG or 3 doses of 40 µg for REC), seroconversion was assessed using the first anti-HBsAg titer between 23 and 365 days after the last vaccine dose. For primary non-responders, seroconversion was assessed in the same way after a second complete vaccination series.
- Population characteristics were compared between ENG and REC patients using Student's t test or chi squared test as appropriate. Seroconversion rates were compared between the two vaccines using the chi squared test.

## Results

- ENG patients (N = 24,677) were older (63.9 vs. 63.1 years), had a higher eKt/V (1.6 vs. 1.5), a higher proportion of diabetics (61.5% vs. 54.9%), fewer patients with congestion heart failure (12.3% vs. 16.1%), lower dialysis vintage (0.8 vs. 1.1 years) and lower hemoglobin (11.2 vs. 11.5 g/dL) compared to REC patients (N = 1,320) (Table 1).
- Seroconversion rates were significantly higher with ENG compared to REC (1st series: 73.7% vs. 64.3%, Δ=9.4% 95% CI: 6.7 % to 12.1%); 1st and 2nd series combined: 78.5% vs. 64.6%, Δ=13.9%, 95% CI: 11.2% to 16.5%) (Figure 1).

## Discussion

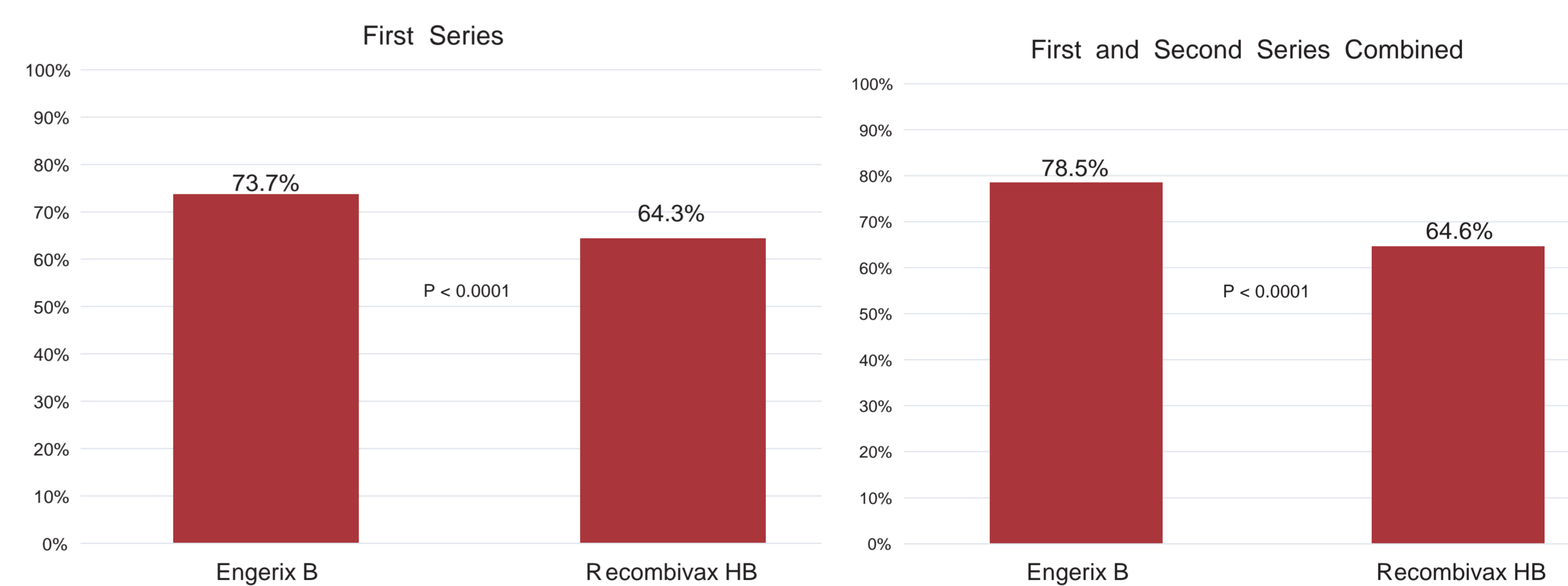
- When administering full vaccination courses as outlined above, Engerix-B yields substantially higher primary seroconversion rates than Recombivax-HB. The same is true when looking at cumulative response rates for the 1st and 2nd series combined. These results hold true even after adjusting for differences in population characteristics.

Table 1: Descriptive statistics of study cohort

Variable	All patients, Mean (SD)	Patients who received ENG, Mean (SD)	Patients who received REC, Mean (SD)	Difference between groups, mean (95% CI)	P Value
Number of patients	25,997	24,677	1,320		
<b>Patient characteristics</b>					
Age (years)	63.9 (14.1)	63.9 (14.1)	63.1 (14.1)	0.8 (0.0, 1.6)	0.04 <sup>a</sup>
Body mass index [kg/m <sup>2</sup> ]	29.7 (9.6)	29.8 (9.7)	29.0 (7.1)	0.8 (0.2, 1.3)	0.01 <sup>a</sup>
Body surface area [m <sup>2</sup> ]	1.9 (0.3)	1.9 (0.3)	1.9 (0.3)	0.0 (0.0, 0.0)	0.59 <sup>a</sup>
Dialysis Vintage [years]	0.8 (1.6)	0.8 (1.5)	1.1 (1.8)	-0.3 (-0.4, -0.2)	<0.0001 <sup>a</sup>
Access catheter [%]	30.0	30.0	29.9	0.1 (-3.2, 3.5)	0.94 <sup>b</sup>
Diabetes [%]	61.1	61.5	54.9	6.6 (3.7, 9.3)	<0.0001 <sup>b</sup>
Congestive heart failure [%]	12.4	12.3	16.1	-3.8 (-11.9, -6.0)	0.0029 <sup>b</sup>
Cancer (excluding skin cancers) [%]	2.4	2.2	3.3	-1.1 (-2.4, 0.5)	0.1 <sup>b</sup>
Hepatitis C positive [%]	5.7	5.7	6.3	-0.6 (-2.1, 0.8)	0.34 <sup>b</sup>
Male [%]	58.0	58.0	58.5	-0.5 (-3.3, 2.3)	0.73 <sup>b</sup>
Race [% white]	68.9	69.0	67.5	1.5 (-1.3, 4.0)	0.32 <sup>b</sup>
<b>Laboratory parameters</b>					
Albumin [g/L]	3.8 (0.4)	3.8 (0.4)	3.8 (0.4)	0.0 (0.0, 0.0)	0.19 <sup>a</sup>
enPCR [g/kg/d]	0.9 (0.3)	0.9 (0.3)	0.9 (0.5)	0.0 (0.0, 0.0)	0.95 <sup>a</sup>
Hemoglobin [g/dL]	11.2 (0.8)	11.2 (0.8)	11.5 (0.8)	-0.3 (-0.3, -0.2)	<0.0001 <sup>a</sup>
Neutrophil: lymphocyte ratio	4.1 (7.2)	4.1 (7.4)	4.0 (2.4)	0.1 (-0.5, 0.6)	0.83 <sup>a</sup>
White blood cell count [1000 µL]	7.3 (2.8)	7.3 (2.8)	7.3 (2.5)	0.0 (-0.2, 0.1)	0.76 <sup>a</sup>

Data are given as mean (SD) for continuous variable, and percentage for categorical variables.  
<sup>a</sup> Student's T Test, <sup>b</sup> Chi-Squared test.  
 For continuous variables, we average the value from the date of the 1<sup>st</sup> dose to last dose of 1<sup>st</sup> HBVvacc series.

Figure 1: Hepatitis B Seroconversion Rates by Vaccine Type



## References

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