

March 2020

## Renal Safety and Racial Disparity in Patients on Antiviral Treatment for Chronic Hepatitis B

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### Recommended Citation

Miller, Matthew; Benjaram, Sindhuri; Kutaimy, Raya; Naylor, Paul; May, Elizabeth; Ehrinpreis, Murray; and Mutchnick, Milton, "Renal Safety and Racial Disparity in Patients on Antiviral Treatment for Chronic Hepatitis B" (2020). *Medical Student Research Symposium*. 40.  
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## Renal Safety and Racial Disparity in Patients on Anti-viral Treatment for Chronic Hepatitis B

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### Background:

Many African Americans (AA) are chronically infected with Hepatitis B (HBV). While antiviral therapy is highly effective, clinical trials suggest a treatment-related decline in kidney function is possible. Given that chronic HBV predominately affects Asians worldwide, most studies have contained few AA patients. We evaluated these treatment-related kidney function changes in our predominately AA patient population.

### Methods:

From 225 HBV patients, we identified 42 patients who were not co-infected with HIV or HCV, had a recent visit, and at least one earlier visit (before Jan 2017). If on treatment with antivirals it must have been for at least 2 years. There were 27 AA (65%) and 15 non-AA (7 Asian, 6 Caucasian, 2 other). There were 24 patients on antiviral treatment and 18 patients not on treatment. Most patients were treated with tenofovir disoproxil fumarate (TDF; n= 19), with the remaining 5 treated with entecavir. Serum creatinine levels (mg/dL) and glomerular filtration rate (GFR; mL/min/1.73m<sup>2</sup>) were obtained from the earliest visit and the most recent visit. The average time between measurements was 7.4 years (range from 2-15; median 6.5).

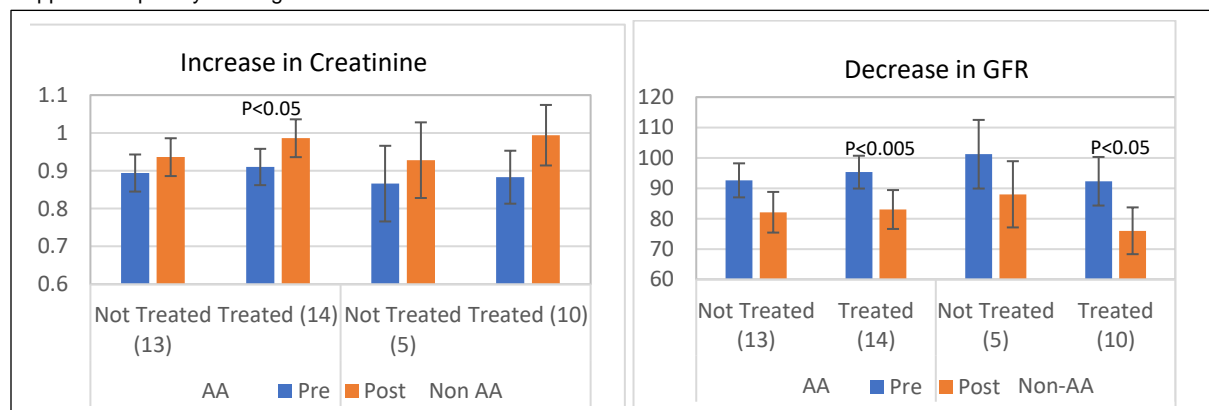
### Results :

The data in the figure below presents the average creatinine and GFR for all patients by race both before and after treatment. The p-value is for pairwise analysis of the change between the two visits. Patients treated with antivirals had nearly double the increase in serum creatinine as compared to untreated patients (treated: 0.091± 0.0439, p<0.05; vs untreated: 0.047 ± 0.045, not significant). There was also a greater decrease in kidney function as defined by GFR for patients on treatment as compared to untreated patients (treated: -13.9 ± 5.0, p<0.05; vs untreated: -11.3 ± 5.9, not significant). The creatinine increase was also significant in AA but not in non-AA (+0.76 for AA, p<0.05; vs +0.11 for non-AA). Racial disparity for GFR was not as noticeable (-12.2/95.2= 13% decrease; p<0.005 for AA, and -16.2/92.3= 18% decrease; p<0.05 for non-AA). When limited to just TDF, the induced increase in creatinine (+0.10; p<0.05) and the decline in GFR (-14; p<0.005) were statistically significant.

### Conclusions:

While few patients had a clinically relevant rise in creatinine and/or decrease in GFR to raise the issue of stopping medication, the value of continuing to monitor especially the AA patients on anti-viral treatment is revealed by our data. The data supports the counselling of AA patients that switching to the newer formulation of tenofovir alafenamide (TAF) which is associated with less renal toxicity than TDF should be strongly considered.

Supported in part by Investigator-Initiated Grant from Gilead Sciences



The decline in kidney function (increase in serum creatinine (mg/dL) and decrease in glomerular filtration rate (GFR; mL/min/1.73m<sup>2</sup>)) is presented for race and treatment. The statistical significance was determined using pairwise analysis. The number of patients is in parentheses for each group. The error bars are the standard error of the mean. Pre is earliest measurement and post is a measurement at least two years after first measurement.