

Is Routine Renal and Liver Laboratory Testing Among PEP Patients On TDF/FTC/DTV Necessary?

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BACKGROUND

- HIV post exposure prophylaxis (PEP) guidelines recommend routine glomerular filtration rate (GFR), aspartate aminotransferase (AST), and alanine transaminase (ALT) at PEP initiation and follow up visits two to six weeks later^{1,2}
- Once daily tenofovir/emtricitabine(TDF/FTC) + dolutegravir(DTV) is a recommended PEP regimen due to its high safety profile^{1,2}
- At New York City (NYC) Sexual Health Clinics (SHC), 28 days of TDF/FTC+ DTV is the first line regimen for patients eligible for PEP who do not report history of renal and severe liver disease
- Testing protocol for patients initiating PEP includes metabolic panels with AST, ALT and calculated GFR
- Patients are advised to return for follow up metabolic panel testing 14-28 days after PEP initiation

OBJECTIVE

- Determine the prevalence of abnormal AST, ALT, and GFR at baseline and follow up testing among patients provided 28 days of TDF/FTC/DTV

METHODS

- Data source:** NYC SHC electronic medical records
- Observation period:** September 2016- December 2017
- Study Population**
 - Cis-gender men or women
 - Received 28 days of TDF/FTC/DTV at NYC SHC
 - Negative rapid HIV test and HIV NAAT at time of PEP initiation
 - No PEP/PrEP provided at SHC within past 90 days
 - Baseline metabolic panel on date of PEP initiation
 - Hepatitis B, C serology within past year or up to 7 days after PEP initiation
- Follow up laboratory testing:**
 - Metabolic panel within 14-42 days of PEP initiation
 - Data were de-duplicated to the first metabolic panel testing performed during the follow up time period
- Outcomes:**
 - Abnormal renal function(RF) and liver function(LF) at baseline and follow up testing
 - GFR results were categorized from Normal to Grade 3
 - AST and ALT results were categorized from Normal to Grade 3
 - RF and LF ≥ Grade 1 were considered abnormal
- Analysis:**
 - Chi-square test was used to compare categorical variables among PEP patients with and without follow up RF and LF testing
 - Multivariate logistic regression evaluated variables associated with follow up RF and LF testing
 - A p value of 0.05 or less was considered statistically significant

RESULTS

- Of 1,255 visits where 28 days of PEP was dispensed, 1115 visits (88.4%) of 1051 unique patients met the inclusion criteria

RESULTS

Table 1: PEP Visit –Level Analysis of Patient Characteristics, by Renal and Liver Function Follow Up Testing at NYC SHC: September 2016- December 2017

Variable	Total N(%)	Follow Up Renal and Liver Function Testing		P value
		Yes N (%)	No N (%)	
Total	1115	575 (100.0)	540 (100.0)	
Age ≥ 40 years	151 (13.5)	81 (14.1)	70 (13.0)	0.58
Foreign born	398 (35.7)	232 (40.3)	166 (30.7)	<.001
Gender/Sexual Behavior				<.001
Men who have sex with men	953 (85.5)	513(89.2)	440 (81.5)	
Men who have sex with women only	73 (6.5)	31 (5.4)	42 (7.8)	
Women	89 (8.0)	31 (5.4)	58 (10.7)	
Race/Ethnicity				0.14
Hispanic/ Latino	345 (30.9)	177 (30.8)	168 (31.1)	
Non-Hispanic Black	330 (29.6)	156 (27.1)	174 (32.2)	
Non-Hispanic White	258 (23.1)	137 (23.8)	121 (22.4)	
Non-Hispanic Other	182 (16.4)	105 (18.2)	77 (14.2)	
Baseline PEP Initiation Testing				
Abnormal RF (GFR< 70 ml/min)	32 (2.9)	14 (2.4)	18 (3.3)	0.37
Abnormal LF (AST or ALT >50 U/L)	95 (8.5)	60 (10.4)	35 (6.5)	0.018
Active Hepatitis B or C Infection	11 (1.0)	6 (1.1)	5 (0.9)	0.84

Table 2: Results of Renal Function Testing at PEP Initiation Visits and First Follow Up Visits (N=575)

Baseline RF	Laboratory Results at Follow Up Visit			
	Normal N (%)	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)
Normal RF (N= 561) (GFR>70 ml/min)	521 (92.8)	39 (7.0)	1(0.2)	0 (0)
Grade 1 RF (N=14) (GFR 50-69 ml/min)	4 (29.6)	10 (71.4)	0 (0)	0 (0)
Grade 2 RF (N=0) (GFR 30-49 ml/min)	0 (0)	0 (0)	0 (0)	0 (0)
Grade 3 RF (N=0) (GFR<30 ml/min)	0 (0)	0 (0)	0 (0)	0 (0)

Table 3: Results of Liver Function Testing at PEP Initiation Visits and First Follow Up Visits (N=575)

Baseline LF	Laboratory Results at Follow Up Visit			
	Normal N(%)	Grade 1 N(%)	Grade 2 N(%)	Grade 3 N(%)
Normal LF (N=515) (AST and ALT< 50 U/L)	480 (93.2)	29 (5.6)	5 (1.0)	1(0.2)
Grade 1 LF (N=53) (AST and/ or ALT 50-100 U/L)	30 (56.6)	20 (37.7)	3 (5.7)	0 (0)
Grade 2 LF (N=6) (AST and/or ALT 101-250 U/L)	1 (16.7)	2 (33.3)	2 (33.3)	1 (16.7)
Grade 3 LF (N=1) (AST and/or ALT >250 U/L)	0 (0)	0 (0)	0 (0)	1 (100)

- 52% of PEP initiates had follow up RF and LF testing with follow up median time of 21 days (IQR: 21-24) after PEP initiation
- Multivariate analysis** revealed that only two variables were more likely to have FU laboratory testing:
 - Abnormal baseline LF (aOR 1.7;95%CI 1.1-2.6)
 - Foreign-born patients (aOR 1.4;95%CI 1.1-1.8)
- Baseline RF and LF testing
 - Majority of abnormal baseline LF and RF testing were grade 1 (RF: 31/32; LF: 77/95)
 - Abnormal LF testing (8.5%;n=95/1115) were more common than abnormal RF testing (3%; n=33/1151)
- Follow up RF and LF testing
 - Majority of abnormal FU labs were grade1 (RF: 49/50; LF: 51/ 64)
 - Abnormal LF testing 11.1% (n=64/575) were more common than abnormal RF testing (8.6%; n=50/575)
- Only twice was a PEP regimen changed due to baseline LF or RF testing**
 - Clinician switched PEP regimen after patient had grade 2 baseline RF
 - One patient stopped PEP regimen on his own after having abdominal pain and grade 2 LF abnormality
- No PEP regimens were changed due to FU RF or LF testing abnormalities.**

DISCUSSION

- Limitations**
 - Only half of patients returned for follow up RF and LF testing; however, this did not vary by age and race categories
 - The number of women in this study was low and there was lower rate of follow up testing compared to men
- Conclusion**
 - The vast majority (>90%) of baseline renal and liver testing was normal at PEP visits among patients with no known history of renal or severe liver disease
 - PEP regimen changes were rarely indicated due to abnormal baseline laboratory testing (0.2%)
 - Follow up renal and liver testing did not result in any changes in PEP regimens
- Implications**
 - As the safety profile of HIV medications used in PEP regimens improves, routine renal and liver may not be necessary for healthy patient population

References

¹ Centers for Disease Control and Preventions. Updated guidelines for antiretroviral post-exposure prophylaxis after sexual, injection drug use, or other non-occupational exposure to HIV- United States, 2016
²PEP for non-occupational exposure to HIV. <https://www.hivguidelines.org/pep-for-hiv-prevention/>. Accessed Feb 1st, 2019.