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[TITLE:] PATTERNS OF RESISTANCE MUTATIONS IN PATIENTS FAILING ON A DIDANOSINE (DDI) AND TENOFOVIR (TNF) CONTAINING REGIMENS

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BACKGROUND: Due to a high rate of early virological failure (VF) with selection of resistance mutations the EMEA does not recommend the coadministration of ddi and TNF unless strictly necessary.

METHODS: From our database we have evaluated the virological outcome of TNF plus ddi based-regimens ($n=92$). Twenty-five of them were antiretroviral naïve and 67 were virologically suppressed for at least 6 months, who had previously been exposed to a median of four regimens (from two to 10) during a median of 65 months (IQR 40–96). Patients began or switched their antiretroviral regimen to a new combination consisting on TDF once daily plus ddi EC once daily (adjusted to body weight) plus a third nucleoside (NRTI) ($n=21$), or a non-nucleoside (NNRTI) ($n=48$) or lopinavir/ritonavir (PI) ($n=23$). Whenever VF was detected, a genotypic resistance test was performed both at VF, at prior to any antiretroviral therapy or in previous episodes of VF if any.

RESULTS: After a median follow-up of 23 months (IQR 19–26), 19 from the 92 developed VF (21%). Seven of the 19 failing patients received a NRTI (lamivudine, $n=5$; abacavir, $n=2$), 11 a NNRTI (efavirenz, $n=7$; nevirapine, $n=4$) and 1 lopinavir/ritonavir, in addition of ddi and TNF. The genotypic analyses at VF detected resistance mutations in 18 patients (95%), and was wild type in the patient treated with PI. In these 18 patients, resistance mutations in the reverse transcriptase gene were never detected at baseline before any antiretroviral therapy and were *de novo* in 16 patients (84.2%) and both "the novo" and emergent of archived mutations in the remaining two. M184V was selected in all the NRTI treated patients (seven of seven). K65R was selected in 11 patients (58%) and L74V in four (22.2%). L100I, K103N/R/T, 106I/M, Y181C and G190E/Q/S were

selected in all the NNRTI treated patients (11 of 11) and emerged in two additional patients (68.4%).

CONCLUSION: These results argue against the use of TDF-ddI plus a NRTI or a NNRTI not only in naïve patients but also in previously suppressed patients. Conversely combinations including lopinavir/ritonavir seem to be virologically safer.

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