VirtualPhenotype[TM] is Concordant With Actual Phenotype: a Retrospective Analysis of Data from VIRA3001.

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BACKGROUND: A randomized prospective study (VIRA3001) demonstrated that using phenotypic resistance information from the Antivirogram[TM] to guide therapy significantly improves outcomes in patients failing their first PI-containing regimen. HIV-1 genotyping assays are faster and less complex to perform but their clinical utility is limited by difficulties in interpreting raw genotypic data. We have developed an interpretation system that delivers the VirtualPhenotype[TM] (vPT) as part of our genotyping system, VircoGEN II [TM].METHODS: HIV sequence data for the PR &RT genes out to codon 400, are obtained by ABI DNA sequencing. For each patient sample the software searches our relational database of over 65,000 genotypes and phenotypes for previous samples with matching mutations. The phenotypes for these are then retrieved and the fold resistance for each drug averaged. The vPTs for the 271 patients in VIRA3001were calculated and compared with the real phenotype for each of the 14 available drugs. In both cases, susceptibility were expressed as fold change in IC[50] with 0-4 being classed as Sensitive (S), >4/10 as Resistant (R).RESULTS: The vPT and real phenotype were concordant in 86%(95%C.I.: 84%-88%; Kappa statistic: 0.75) of cases. When combining intermediate and resistant phenotypic susceptibility categories, the vPT and real phenotype were concordant in 90%(95% C.I.: 88%-91%; Kappa statistic: 0.71) of cases. Major discordancies (S=R and R=S) were observed in only 3%of cases (95%C.I.: 2%-4%).CONCLUSIONS: These analyses indicate that the vPT is highly concordant with the real phenotype, which is predictive of response to therapy. This supports the utility of the VirtualPhenotype[TM] as a tool to assist therapeutic decision-making.KEYWORDS: Phenotypes; Resistance; Virtual

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