ULTRASENSITIVE ASSAY TARGETING HIV-1 PROMOTER REGION DETECTS VIRAL INTRACELLULAR ACTIVITY IN BLIP EXPERIENCED PATIENTS ON ART FROM DRIED BLOOD SPOTS

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Background:
Dried Blood Spots (DBS) have been widely used in certain HIV clinical settings, including early infant diagnostics and drug resistance surveillance, as an alternative specimen type, for hard-to-reach populations and in resource limited settings. Although there are commercially available molecular assays that detect HIV-1 to low levels (<20cpy/mL) in venous clinically collected samples, there are limited commercially avaliable and registered assays that utilse a DBS sample type. In this study we investigated detection sensitivity to identify presence of HIV-1 in DBS samples by comparing the GeneXpert system to our recently developed πCode assay.

Methods:
45 DBS samples were obtained from HIV positive patients virally suppressed on ART, comprising patients without recent blips (n= 21) and patients with blips (n= 24) (defined as two blips above 20-200 copy/mL within a 2-year period). DBS were tested on the GeneXpert HIV-1 qualitative assay and the πCode assay, targeting the highly conserved "R" region of the LTR.

Results:
HIV-1 was detected using the πCode assay and GeneXpert with an overall sensitivity of 93% and 43% respectively. Furthermore, the πCode assay detected HIV-1 in 100% of blip patients (n=21) and 88% for non-blip patients (n=24): the πCode assay failed to detect presence of HIV-1 with 12% (3 samples out of 24 DBSs). We did further analysis to investigate reasons of failure of HIV detection. We revealed those 3 non-blip samples had very low levels of CA-HIV-1 RNA transcripts and total HIV-1 DNA levels by our standard piCde analysis using 5ml of whole blood. Therefore HIV-1 detection on those 3 non-blip DBSs were difficult to identify the presence of HIV-1.

Conclusion:
Our study demonstrated that the πCode assay has a high sensitivity, compared with the GeneXpert system, to detect HIV-1 from DBS samples from virally suppressed patients. We identified a novel possibility to assess DBS for HIV treatment monitoring, although our study sample size needs to be increased to confirm our initial findings.

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