HPV detection by vaginal self-sampling and urine collection in women living with HIV AUTOCol study

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BACKGROUND

Vaginal self-sampling (VSS) has been implemented as primary cervical cancer screening tool in several countries around the world. Urine collection (UC) can be an alternative if women are uncomfortable with genital sampling. Women living with HIV (WLHIV) are at increased risk of cervical intraepithelial lesions. The main objective of the study is to assess the acceptability of VSS coupled with USS among WLHIV within the population of the COREVIH Ile-de-France (IDF) Paris Nord territory. The secondary objectives of the research are evaluating the quality of the VSS and USS performance, estimate the prevalence of HR-HPV in both samples (VSS and USS), study the associated factors with the acceptability of self-sampling, and evaluate the feasibility of self-sampling.

METHODS

AUTOCol is a multicentre prospective study enrolling WLHIV for cervical cancer screening in 4 hospitals from COREVIH IDF Nord. Both VSS (FLOQSwab in Mswab medium, Copan, Italy) and UC (Colli-pee, Novosanis, Belgium) were offered. High-risk human papillomavirus (HR-HPV) were detected with AnyplexII (Seegene, South Korea) by semi-quantitative PCR.

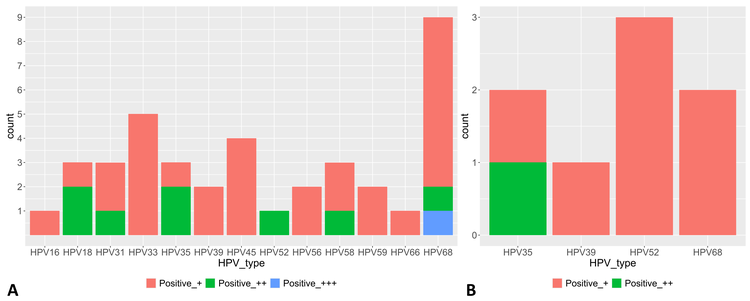


Figure 2: Description of discordant HR-HPV with semi-quantitative evaluation (+ low VL, ++ intermediate VL, +++ high VL).
A) 39 HR-HPV in 34 WLHIV detected in VSS while negative in UC
B) 8 HR-HPV in 7 WLHIV detected in UC while negative in VSS

Vaginal self-sampling and urine collection are well accepted by women living with HIV and preferred to cervical smear
They are both suitable for HR-HPV detection
Vaginal self-sampling appears to be more sensitive when HR-HPV viral load is low

RESULTS

Inclusion: 201 WLHIV

- Between June 2023 and January 2024
- Median age : 51 years (IQR = 43-58)

Immunovirological status:

- HIV viral load: 91% undetectable (n=182/199, VL <50 c/mL)
- Median CD4 T-cell count: 770/mm^3 (IQR = 560-990) with 5 WLHIV <200/mm^3 CD4 cells

Acceptability:

- Acceptance rate to carry out self-sampling : 87% (n=175/201)
- Main reason for refusal : fear of failing (n=14/26)
  - Felt when performing the test:
    - UC: no pain 98% (n=156/160)
    - VSS: no pain 83% (n=140/169), discomfort 10% (n=17/169)
- Patients preferred the UC for 80% (n=129/162) and the VSS for 74% (n=128/173), than the cervical smear performed by a health professional

Sample collection:
174 VSS and 169 UC → 167 paired samples
Sampling method validity: only one unsatisfactory sample for each sampling method

HPV infections prevalence on VSS:

- 43.4% had at least one HR-HPV (n=75/173)
- 33.3% of them had multiple HR-HPV infections (n=25/75)
- 10.7% were positive for HPV16 (n=8/75)
- HPV68 was the most prevalent type (n=18/75, 24.0%)

VSS and UC comparison for HPV detection:
Concordance: 83% of agreement,
kappa = 0.64 (Fig.1, Table 1)
Discordant results (Fig.2)

- 39 HR-HPV from 34 WLHIV were detected in VSS and negative in UC
- 8 HR-HPV from 7 WLHIV were detected in UC and negative in VSS
- HR-HPV viral load estimation was low for 37 of these 47 discordant HR-HPV (79%)

CONCLUSIONS

VSS is a good alternative for women needing frequent cervical cancer screening or are reluctant to undergo gynecological examination.
UC should only be proposed if women refuse any genital sampling.

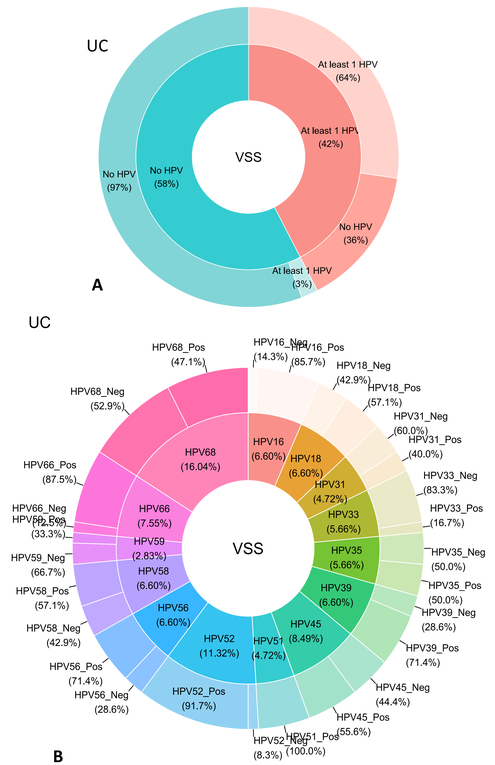


Figure 1: Pie-donut plots representing concordance of HPV detection between VSS and UC.
A) concordance for at least one HR-HPV detection
B) concordance for the 14 HR-HPV detection

HR-HPV	Agreement	Kappa coefficient
HPV16	99.4	0.92
HPV18	98.2	0.72
HPV31	98.2	0.56
HPV33	97.0	0.28
HPV35	97.0	0.53
HPV39	98.2	0.76
HPV45	97.6	0.70
HPV51	100.0	1.00
HPV52	97.6	0.83
HPV56	98.8	0.83
HPV58	98.8	0.72
HPV59	98.8	0.50
HPV66	99.4	0.93
HPV68	93.3	0.56
All HR-HPV	83.0	0.64

Table 1: Percentage of agreement and kappa's coefficient for HR-HPV detection in paired VSS and UC samples by HR-HPV type and overall (n=165).