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Role of self-sampling for the diagnosis of human papillomavirus in rural areas from Cuenca Ecuador: Acceptance, sensitivity and specificity among urine sampling, self-sampling and clinician sampling.

13 - Self-sampling

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Background/Objectives: Background: During 2020, 1534 new cases of cervical cancer were reported in Ecuador and 813 women died from this cause. Pap smear has decreased mortality of (CC), however in Ecuador 41.6% of women in their reproductive age have been never screened. Different barriers for CC screening have been identified, among them: long waiting times, pain, embarrassment, lack of risk perceptions are related with this low coverage. High sensitivity tests for primary screening of HPV are useful for an early detection of cervical pathology. Self-sampling techniques could overcome barriers and increase participation in screening and participation. Objectives 1.- To compare the sensitivity and specificity of urine and vaginal self-sampling test versus clinician sampling test, for HPV diagnosis. 2.- To compare the acceptability of urine and vaginal self-sampling methods versus clinician sampling among rural women

Methods: A diagnostic test study was conducted in a rural parish of Cuenca, Ecuador. A total of 120 women participated. Each participant self-collected urine and vaginal samples and underwent clinician sampling for HPV testing. The latter was considered as the golden standard. All three samples were processed with the same amplification and hybridization protocol for HPV detection (Hybribio) following the manufacturer's instructions. After sample collection a questionnaire to qualify device and technique and individual acceptability was applied and additional overall preference of three sample tests was evaluated

Results: A total of 120 women participated main chracteristicas are: median age 35 years; 40.8% married; 46.7% had a primary level of education; median age of sexual onset, 17.6 years Sensitivity The prevalence of any type of HPV with clinician sampling was 15.0%, 17.5% with urine sampling and 18.3% with vaginal self-sampling. Self-sampling sensitivity reached 94.4% (IC 74.2-99.9), and specificity 92.1% (IC 85.2-95.9). Urine sampling had a sensitivity of 88.8% (IC 67.2, 96.9), and specificity 94.1% (IC 67.2-96.9). The negative predictive value was 98.9% (IC 94.2-99.8) for vaginal self-sampling and 97.6% (IC 92.6-99.4) for urine sampling. Conclusions: This study shows that vaginal and urine self-sampling methods have similar sensitivity and specificity compared with clinician sampling for the diagnosis of HPV. The correlation between HPV genotypes among the three tests is satisfactory. Acceptability Compared with clinician sampling, both vaginal self-sampling OR 20.12 (7.67-52.8) and urine sampling OR16.63 (6.79-40.72), were more comfortable, granted more privacy: vaginal self-sampling OR 8.07 (3.44-18.93); urine sampling OR 19.5 (5.83-65.21, were less painful: vaginal self-sampling OR 0.07 (0.03-0.16); urine sampling OR 0.01 (0-0.06) and less difficult to apply: vaginal self-sampling OR 0.16 (0.07-0.34) urine sampling OR 0.05 (0.01-0.17). Overall preference has shown an advantage for vaginal self-sampling 4.97 (2.71-9.12). No statistically significant preference was demonstrated with urine self-sampling versus clinician sampling.

Conclusions: This study shows that vaginal and urine self-sampling methods have similar sensitivity and specificity compared with clinician sampling for the diagnosis of HPV. The correlation between HPV genotypes among the three tests is satisfactory. Self sampling methods have a high acceptance in rural communities. Doubts on the reliability of self-sampling often appears to be a limitation on the acceptability.