ELECTRoDE BIOCHIPS COUPLED TO ISOTHERMAL AMPLIFICATION LAMP TECHNIQUE IN DIAGNOSTICS OF CERVICAL PRECANCER

**Introduction/Background** Persistent infection with high-risk human papillomavirus (hrHPV) is a major etiological factor of cervical cancer. Hence, the effectiveness of cytological screening can be improved by the implementation of hrHPV tests. Current methods of HPV detection frequently involve expensive reagents and instrumentation or need for skilled personnel. Electrochemical methods of detection may address these challenges since they offer rapid detection times and require small, inexpensive instrumentation that is simple to operate.

**Methodology** We compared two different bioplatforms. Both utilized loop-mediated isothermal amplification (LAMP) to amplify HPV DNA from two most oncogenic high-risk HPV types, HPV 16 and HPV 18, by combining loop-mediated amplification (LAMP) of viral DNA, its separation using magnetic beads and detection with an electrochemical technique – amperometry – at carbon-based electrode chips.

**Results** Using magnetic beads, we detected HPV DNA directly from crude lysates of cervical cancer cell lines (CaSi, SiHa, HeLa) and from 19 clinical samples (patients with high-grade squamous intraepithelial lesions or healthy controls), without DNA extraction step [2]. Detection was possible from as little as 10 cells. We obtained excellent concordance of our assay with PCR, reaching 100% sensitivity for both genotypes, 81.82% specificity for HPV 16 and 94.12% specificity for HPV 18. Later, we omitted magnetic beads to detect HPV directly on gold electrodes, obtaining very good sensitivity and specificity when determining HPV16/HPV18 infection in 15 clinical samples when compared to the PCR [3].


**REFERENCE**


**2022-RA-900-ESGO** PERFORMANCE OF A LAMP-BASED ELECTROCHEMICAL BIOASSAY FOR DETERMINATION OF HIGH-RISK HPV INFECTION IN CLINICAL SETTINGS

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**Introduction/Background** Persistent infection with the high-risk types of HPV is considered a crucial initiating factor in cervical carcinogenesis. Tests detecting the presence and especially the activity of HPV infection offer a new quality to screening and diagnostics. The limitation of these tests is, however, the price. Standardly used PCR tests are time consuming and instrument-intensive. A perspective alternative, the LAMP isothermal amplification coupled to an electrochemical detection, is presented.

**Methodology** We developed an assay for parallel detection of two most oncogenic high-risk HPV types, HPV 16 and HPV 18, by combining loop-mediated amplification (LAMP) of viral DNA, its separation using magnetic beads and detection with an electrochemical technique – amperometry – at carbon-based electrode chips.

**Results** Optimization of the method was first published on pilot files with a small number of cases. Later, we carried out a small clinical study using electrochemical LAMP-based assay for detection of HPV 16/18 DNA in LBC samples obtained from 61 women undergoing conisation for cervical precancerous lesion. HPV 16 and 18 assays were performed by LAMP isothermal amplification combined with electrochemical reading. The results were confirmed by PCR amplification with gel electrophoresis and two commercial HPV assays (Cobas and INNO-LiPA). The best concordance was obtained with the PCR, reaching very good specificity for both genotypes (>93%) and positive and negative predictive values over 90%.

**Conclusion** These data indicate that the EC-LAMP isothermal amplification may serve as an interesting alternative tool for rapid screening of oncogenic HPVs.

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**REFERENCES**


epithelium cells are considered as promising diagnostic markers of cervical dysplasia. MicroRNA-based diagnostic test-systems can provide a helpful addition to traditional diagnostic techniques.

Methodology NOVAprep-miR-CERVIX is a new test-system based on RT-qPCR analysis of six miRNAs (miR-21-5p, miR-29b-3p, miR-145-5p, miR-451a-5p, miR-1246-5p and miR-1290-3p) in material of cervical smear. Test-system includes quality of material control and control of enzymatic reaction efficacy. Machine learning based of random forest algorithm was applied for RT-qPCR results evaluation. Cervical smear samples were obtained from 226 women: 114 samples of normal epithelium and 112 samples of cervical epithelium with high-grade intraepithelial lesion (HSIL) or carcinoma in situ (CIS) as a result of cytological evaluation. Moreover, any of HSIL/CIS diagnosis was confirmed histologically.

Results The 38 samples from 216 (17.8%) did not pass quality controls and were excluded from analysis. NOVAprep-miR-CERVIX Index (miR-CERVIX-I varied from 0 to 1) was calculated on the base of results of six miRNA analysis for remaining 178 samples. Difference in miR-CERVIX-I was statistically significant in two groups of samples formed on the base of cytological/histological diagnosis (figure 1). Normal condition of cervical epithelium (miR-CERVIX-I < 0.49) was diagnosed with sensitivity 79.2%, specificity 80.46%. HSIL was diagnosed with sensitivity 70.83%, specificity 97.22% (miR-CERVIX-I > 0.78). Moreover, intermediate value of miR-CERVIX-I (between 0.5 and 0.77) is supposed to reflect condition of low-grade intraepithelial dysplasia.

Methodology A systematic literature review of MEDLINE (PubMed) and bibliographic cross-referencing was performed to identify articles covering dermoscopy features of common and atypical nevi, melanosis and melanoma. Articles were included if dermoscopy was performed on genital lesions and dermoscopy features of pigmented genital lesions were described and extractable.

Results A total of 19 articles with 455 dermoscopy cases of genital lesions could be extrapolated from the published literature. Identified dermoscopy criteria for genital melanoma included asymmetry of color and or structure (92%), followed by blue/white or blue/grey veil (69.2%). Genital melanosis showed a diffuse pigmentation in 51.4% and a ringlike pattern in 27.8% of described cases. Features identified in common genital nevi included a homogeneous brown-gray pigmentation or brown structureless areas and were described in 35.1%. A globular pattern was described in 35.7%.

Conclusion Clinically pigmented genital lesions may look alarming, however the application of dermoscopy may help to differentiate benign melanosis and common genital nevi from melanoma.

Abstract 2022-RA-1115-ESGO Figure 1

Conclusion NOVAprep-miR-CERVIX can be applied for cervical dysplasia diagnostic and management as a test system complimentary to standard methods.

Abstract 2022-RA-1115-ESGO

Introduction/Background Diseases of the genital area cover a broad spectrum of benign and malignant disorders, that range from benign inflammatory conditions to malignant and potentially lethal diagnoses (i.e melanoma). The diagnosis of pigmented genital lesions imposes some diagnostic challenges. The application of dermoscopy can help to differentiate between benign genital lesions and malignant melanoma.

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