The accuracy of p16/Ki-67 dual immunocytochemical staining in detecting high grade lesions in cervical smears with low grade abnormalities: Our experience from a pilot study

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Introduction & Aims: HPV testing is used as a means of triaging cervical smears with low grade squamous abnormalities or as part of co-testing with cytology. While HPV testing has a high sensitivity, it has a low specificity in detecting cervical intraepithelial neoplasia grade 2 and above (CIN 2+) leading to unnecessary colposcopy referrals. We investigate the accuracy of the p16/Ki-67 dual immunocytochemical stain in determining the presence of CIN 2+ lesions and its potential as a superior biomarker for triage.

Materials & Methods: 97 cases of liquid based cervical smears with squamous abnormalities and corresponding histology were collected. The smears were then subjected to the dual stain and HPV testing. The sensitivity and specificity of cytology, dual stain and HPV testing were then calculated using CIN 2+ on histology as a reference standard.

Results: The sensitivity and specificity of the dual stain was 93.7% and 76.5%, cytology was 77.8% and 88.2% while HPV testing was 85.7% and 14.7%. The use of dual stain was estimated to reduce the number of unnecessary colposcopy referrals by significant numbers in women with ASCUS and LSIL if it were used as a triage marker compared to HPV and cytology co-testing.

Conclusion: The P16/Ki-67 dual stain is more specific than HPV testing when triaging low grade and atypical cytology specimens and may help to reduce the number of unnecessary colposcopy referrals. More studies should be performed to further evaluate its role in cervical cancer screening programs.

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