Clinical validation of p16/Ki-67 dual-stained cytology triage of HPV-positive women: Results from the IMPACT trial

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Study Objective

To assess the performance of p16/Ki-67 dual-stain immunocytochemistry for identification of cervical intraepithelial neoplasia Grade 2/3 or greater in women identified as HPV positive at baseline.

Study Population

A prospective observational cervical cancer screening of 35,263 women attending routine cervical cancer screening visits at 32 clinical sites across the US.

Study Design

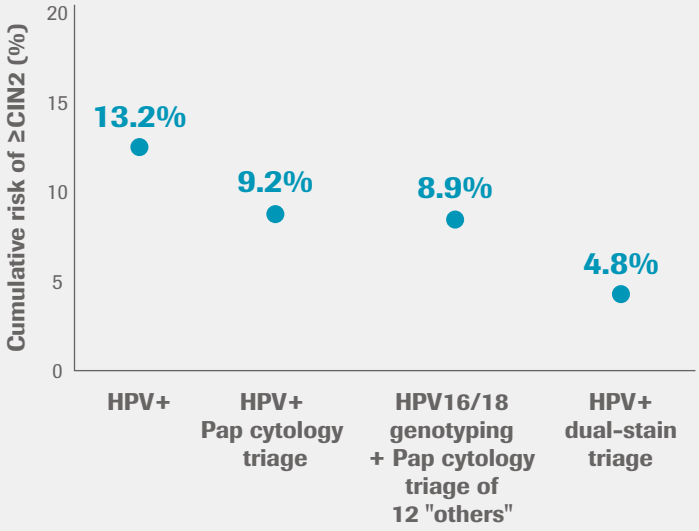
All cervical samples had HPV and cytology testing followed by colposcopy/biopsy-based disease ascertainment for women with a positive screening test.

- **Phase I** - Baseline (cross-sectional): All women referred to colposcopy/biopsy were tested with dual-stain. Women who met the clinical endpoint (ie, biopsy-confirmed ≥CIN2 after the baseline colposcopy/biopsy visit) exited the study
- **Phase II** – 1-year follow-up: Women without CIN2 or greater were retested after 1 year

Study Results

- Dual-stain alone showed a significantly higher sensitivity for the detection of ≥CIN2 in HPV-positive women compared to Pap cytology combined with HPV16/18 genotyping or Pap cytology alone. Similar observations were made for ≥CIN3
- A very low cumulative 1-year risk for disease was shown in HPV-positive women with a dual-stain negative test result, which was significantly lower than the respective risks when using Pap cytology with HPV16/18 genotyping or Pap cytology alone
- A significantly higher efficiency was observed by the lower number of colposcopies to be performed per ≥CIN2 detected by dual-stain alone versus by HPV16/18 genotyping with Pap cytology triage since the triage with dual-stain alone would have referred significantly fewer women to colposcopy

1-year cumulative risk of ≥CIN2 in HPV-positive women



Conclusion

The IMPACT trial results showed that dual-stain-based triage provided significantly higher sensitivity than cytology-based triage and better reassurance against ≥CIN2, thus validating the effectiveness of using dual-stain as a triage for HPV-positive women to better stratify a woman's risk of disease and identify more high-grade disease earlier in the screening process.

Roche Diagnostics Corporation | 9115 Hague Road Indianapolis, IN 46256